

Fundamental Information about the Group

Merck

We are a global science and technology company headquartered in Darmstadt, Germany. With a history of nearly 350 years, we are the oldest chemical and pharmaceutical company in the world. In line with our strategic direction, Merck comprises three business sectors: Healthcare, Life Science, and Performance Materials, which encompass the Group's six businesses.

In Healthcare, we discover, develop and manufacture prescription medicines used to treat cancer, multiple sclerosis, and infertility, among other things, as well as over-the-counter pharmaceutical products for colds and pain. Our products help millions of people around the world.

In Life Science, we conduct research for researchers, providing scientists with laboratory materials, technologies and services. Our aim is to make research and biomanufacturing easier, faster and more successful.

Performance Materials develops specialty chemicals and materials for demanding applications – from liquid crystals and OLED materials for displays to effect pigments for coatings and cosmetics to high-tech materials for the manufacture of integrated circuits.

We hold the global rights to the Merck name and brand. The only exceptions are Canada and the United States. In these countries, we operate as EMD Serono in the biopharmaceutical business, as MilliporeSigma – following the completed acquisition of Sigma-Aldrich – in the life science business and as EMD Performance Materials in the high-tech materials business.

Apart from our three business sectors, our financial reporting presents the five regions Europe, North America, Asia-Pacific (APAC), Latin America as well as Middle East and Africa (MEA). As of December 31, 2016, we had 50,414 employees worldwide, which compares with 49,613 on December 31, 2015.

Healthcare

Our Healthcare business sector comprises the four businesses Biopharma, Consumer Health, Biosimilars, and Allergopharma. Since 2015, Belén Garijo has been the CEO of the Healthcare business sector and member of the Executive Board. In 2016, Healthcare generated 45% of Group sales and 43% of EBITDA pre exceptionals (excluding Corporate and Other), making it the largest of our three business sectors. The regions Europe and North America generated 60% of Healthcare's net sales in 2016. In recent years, we have steadily expanded our presence in growth markets. In 2016, Asia-Pacific and Latin America accounted for 33% of sales.

Biopharma

Our Biopharma business discovers, develops, manufactures and markets innovative pharmaceutical and biological prescription drugs to treat cancer, multiple sclerosis, infertility, growth disorders as well as certain cardiovascular and metabolic diseases. Biopharma is the largest of our Healthcare businesses. We operate in four franchises: Oncology, Neurology/Immunology, Fertility, General Medicine & Endocrinology. Our streamlined R&D pipeline positions us with a clear focus on becoming a leading science-driven innovator in oncology, immuno-oncology and immunology, including multiple sclerosis.

In 2016 we reinforced our commitment to growing our immunology pipeline to provide new options to better the lives of people with immunological diseases as we prepared for the potential launch of cladribine tablets. Our activities included major milestone accomplishments and an impactful presence at key medical meetings around the world.

New data on Rebif®, Biopharma's top-selling drug and leading multiple sclerosis (MS) therapy, and investigational cladribine tablets were presented at both the American Academy of Neurology's (AAN) Annual Meeting in April 2016 and the Congress of the European Academy of Neurology (EAN) in May 2016. In addition, results of more than 30 clinical studies were presented at the world's largest international MS conference, the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in London, United Kingdom.

In June 2016, we reached a major regulatory milestone with the submission for registration of cladribine tablets to the European Medicines Agency (EMA). We believe that cladribine tablets, if approved, could lead to high and sustained efficacy through selective modulation of B and T cells resulting in lasting resolution of inflammation. The additional data we have gathered over the past four years provides better characterization of the safety and tolerability profile and this coupled with a unique oral short course will serve as an important therapeutic advance for patients with relapsing-remitting multiple sclerosis (RRMS).

In July 2016, we announced the EMA's acceptance for review of the Marketing Authorization Application (MAA) for the investigational product cladribine tablets for the treatment of RRMS.

We also presented data on atacicept, our investigational treatment for systemic lupus erythematosus (SLE) at the 2016 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting held in November. Although the primary endpoint was not met in the overall study population of the ADDRESS II Phase IIb, multicenter study on

atacept in patients with SLE, there was a trend favoring atacept with statistical significance achieved in a pre-specified sensitivity analysis of the primary endpoint using treatment Day 1 as baseline (rather than screening visit). Additionally, analyses of a predefined subpopulation of patients with high disease activity demonstrated statistically significant treatment effects of atacept when compared to placebo.

Erbix[®] (cetuximab) remains the second best-selling drug in the portfolio of the Biopharma business and is the company's flagship product in oncology. The product is a standard of care for patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer (mCRC) therapy, as well as both recurrent/metastatic and locally advanced squamous cell carcinoma of the head and neck (SCCHN).

We continue to invest in Erbix[®] and are committed to making it available to those patients whom it will benefit most. In April 2016 we reached a major milestone regarding its expansion in growth markets with the positive results of the pivotal Chinese Phase III TAILOR study.

In addition, we continued to support our goal of improving care for patients with mCRC by further advancing in the area of liquid biopsy technologies through collaborations. In 2016, we became the first pharmaceutical company to collaborate with multiple diagnostic providers to support RAS biomarker testing, with new agreements announced with Biocartis and Amoy Diagnostics Co., Ltd. for different testing technologies to meet the needs of various laboratory segments. These agreements follow our first collaboration with Sysmex Inostics, which achieved a notable milestone in 2016, when the liquid biopsy technology we are co-developing received CE Mark approval in April.

Importantly, through another key collaboration, our strategic alliance with Pfizer Inc., USA, we continued to make progress in the development and envisaged commercialization of avelumab*, an investigational fully human anti-programmed death-ligand 1 (PD-L1) antibody.

The positive results from JAVELIN Merkel 200, the pivotal Phase II study in patients with metastatic Merkel cell carcinoma (MCC) treated with avelumab in second or subsequent lines of therapy, were presented at the American Society of Clinical Oncology (ASCO) 2016 annual meeting. These results supported the submission and acceptance of the Biologics License Application to the U.S. Food and Drug Administration (FDA), as well as the Marketing Authorization Application to the European Medicines Agency. Additionally, we initiated two pivotal Phase III trials for avelumab in 2016, including a combination trial with axitinib for the first-line treatment of renal cell carcinoma and as a first-line treatment for ovarian cancer.

These pivotal trials are part of the larger clinical development program for avelumab, known as JAVELIN, which involves at least 30 clinical programs and more than 4,000 patients evaluated across

more than 15 different tumor types. As part of the strategic alliance, we are also advancing our co-promotion of Pfizer's anaplastic lymphoma kinase (ALK) inhibitor Xalkori[®] (crizotinib), indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ALK-positive. Xalkori[®] is being co-promoted in two waves, the first of which began in 2015 in the United States, Canada, Japan, and five EU countries (France, Germany, Italy, Spain, and the United Kingdom). The second wave began in 2016 including Argentina, China and Turkey.

As part of our efforts in immuno-oncology we have an exclusive strategic collaboration and license agreement with Intrexon Corporation to develop and commercialize Chimeric Antigen Receptor T-cell (CAR-T) cancer therapies.

An important growth driver for our Biopharma business is our fertility portfolio, offering products that help couples to conceive a child, ranging from drugs to technologies. Infertility has become a key topic globally due to the current trend towards delaying childbirth. We see a steadily increasing demand in growth markets, fueling current and future sales. In addition, we are facing a rapidly changing environment in the fertility market, with commoditization and price pressure in the drugs business, more educated patients and an increasing importance of Fertility Technologies. The strategic innovation of Merck's fertility business model to develop from the world market leader in fertility treatments into an integrated fertility treatment partner focuses on turning these trends into opportunities for Merck and will drive further growth. The first step to achieve this goal was to extend our existing drug portfolio into our continuously expanding innovative technologies offering.

We are the only company to offer recombinant versions of the three natural hormones needed to treat infertility as well as a complete and clinically proven portfolio for every stage of the reproductive cycle. In early 2016, our portfolio of drugs was further complemented by the improved Gonal-f[®] prefilled pen, a new pen version including various advanced features designed to facilitate administration for patients.

Our Fertility Technologies business expanded and is now providing solutions for all key steps of in vitro fertilization (IVF). Our automated vitrification instrument Gavi^{™**} can now freeze oocytes and embryos at key stages. For the incubator Geri^{™**} an annotation software was introduced (Geri[™] Connect & Assess 1.0), and with a humidified incubation feature the incubation environment now resembles the conditions in the uterus more closely. A new version of the incubator Geri^{™+} allows for use with the Early Embryo Viability Assessment (Eeva[®]) Test, for which a new software version was launched. With Geri[™] medium we introduced a new single-step medium supporting undisturbed embryo growth. Finally, our innovative witnessing and tracking system Gidget[™] helps to reduce the potential for error and improves lab workflows. Key parts of our technologies portfolio were made available for clinical use in Europe in 2016, and now are also marketed in Canada and Japan.

* Avelumab is not yet approved for any indication in any market. The EMA has validated the Marketing Authorization Application for avelumab for the treatment of metastatic MCC, marking the first acceptance of an EU market authorization application to review the safety and efficacy results for this investigational product. The U.S. FDA has also accepted the Biologics License Application for avelumab for the treatment of metastatic MCC, marking the first acceptance of an application by the U.S. FDA to review this investigational product.

** Gavi[™] and Geri[™] are not available in the United States.

In June, the Global Fertility Alliance welcomed two new members: Zeiss (Carl Zeiss AG, Oberkochen) and Hamilton Thorne Ltd., USA. The alliance paves the way forward into the future of fertility treatment and adds to our strong basis in the drug business and our highly innovative Fertility Technologies business.

Every day, 55 million patients around the world are using our trusted general medicine and endocrinology (GM&E) medications. Today Concor[®], Euthyrox[®], Glucophage[®], and Saizen[®] are high-value brands and market leaders in many key markets around the world. As a result, in terms of sales GM&E is the largest business franchise of the Healthcare business sector, contributing significantly to the overall profitability of Biopharma and Merck. Although no longer patent-protected, the brand equity built over decades makes our flagship products cornerstones for the treatment of chronic cardiovascular, metabolic and endocrine diseases.

Concor[®], containing bisoprolol, is the leading beta-blocker for chronic cardiovascular diseases such as hypertension, coronary artery disease and chronic heart failure. Euthyrox[®], with the active ingredient levothyroxine, is the leading treatment for hypothyroidism, a disease with high prevalence but still low diagnosis in most emerging markets. Glucophage[®], containing the active ingredient metformin, is the drug of choice for first-line treatment of type 2 diabetes. In October 2016, metformin received a positive CHMP opinion for treatment of type 2 diabetes patients with moderate renal impairment (CKD stage 3), which will be reflected in a label change in Europe. This will allow Glucophage[®] and other metformin products to be used safely by a larger group of patients with type 2 diabetes. The indication for Glucophage[®] is being extended to include prediabetes and has been granted approval in 12 markets around the world.

We also help to raise awareness and education in the areas we operate in, such as thyroid diseases. Highlights include our continuous engagement in International Thyroid Awareness Week and our partnership with the Royal Health Awareness Society (RHAS) of Jordan, signed in October.

Saizen[®] (somatropin) is our main endocrinology product and is indicated for the treatment of growth hormone deficiency (GHD) in children and adults. Saizen[®] is delivered with the easypod[™] electromechanical injection device, the only growth hormone injection device of its kind. easypod[™] is able to wirelessly transfer data such as injection times, dates and doses to the web-based software system easypod[™] connect, making it easier for healthcare practitioners and patients to ensure adherence and reach their treatment goals.

As part of our continuous commitment to deliver high-quality medicines to our patients, we are continuously investing in our manufacturing network across the globe. In 2016, we completed the construction of a new facility in Nantong, China, expanded our plant in Rio de Janeiro, Brazil, and initiated the construction of a new packaging center in Darmstadt, Germany, in order to meet the increasing worldwide demand for our General Medicine products Glucophage[®], Concor[®] and Euthyrox[®]. In order to meet the increasing worldwide demand for our biotech portfolio of medicines, we completed the expansion of our plant in Tres Cantos, Spain. In Aubonne, Switzerland, we pushed forward with the construction of our new packaging center.

Consumer Health

In our Consumer Health business we focus on consumer-centric innovation under the umbrellas of several strategic brands such as Neurobion[®], Bion[®], Seven Seas[®], Nasivin[®], Femibion[®], and Dolo-Neurobion[®], as well as Vivera[®]/Floratil[®], Sangobion[®], Vigantolletten[®], Apaisyl[®], and Kytta[®]. Our latest innovations are the probiotic Vivera and the Femibion BabyPlanning line extension. We aim at emotionalizing these over-the-counter and food supplement brands so that they become irresistible love brands in the eyes of our consumers and customers alike. Most of these brands are fully aligned with the newly established purpose of the Consumer Health business: "We exist to prepare society for a new era of humans living 100 healthy years."

Global megatrends favor the future growth of the Consumer Health business. People are becoming more health-conscious and take care of their own physical well-being. Preventive healthcare and as little invasive medication as possible are growing in importance – in both established and developing markets, the latter characterized by a growing middle class with specific needs. And people and societies are growing older than ever before. This is why we developed and started establishing a movement around our new purpose to actively drive change in the societies we are operating in, all under the independent label and motto "WE100[®] – young for old, old for young."

We are currently among the top 15 players in the global OTC market and already generate more than 50% of our annual sales in developing growth markets. In particular, markets such as Chile, Brazil, the United Kingdom, South Africa, Thailand, Indonesia, India, Malaysia, and the Philippines are delivering significant growth rates. To further align the regional with the strategic brand strategies and to even better focus on efficient region-brand combinations, we have reorganized our regional structure.

Biosimilars

Our Biosimilars business is committed to providing access to high-quality biologics to more patients all over the world. In addition, we are developing a biosimilars portfolio focused on oncology and inflammatory disorders through both in-house research and development expertise in biologics and partnerships with other biosimilar players. In 2016, we advanced our pipeline well into clinical development, with our adalimumab Phase III study recruiting the first patient and finishing recruitment in the same year. Biosimilars is an attractive market in which we are well-positioned, building on existing strengths and capabilities across the biosimilars value chain.

Merck has strategic alliances with Dr. Reddy's in India to co-develop multiple cancer drugs and with Bionovis in Brazil to supply the Brazilian market with biological products under the Productive Development Partnership (PDP) policy of the Brazilian Ministry of Health.

Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017.

Allergopharma

Our allergy business Allergopharma is one of the leading companies in the field of allergy immunotherapy (AIT). The Allergopharma portfolio includes a diverse spectrum of approved allergen products that meet high quality standards. AIT (hypo-sensitization, desensitization, specific immunotherapy) is the only causal therapy for treating allergies to unavoidable allergens.

We manufacture products to diagnose and treat type 1 allergies such as hay fever or allergic asthma. Merck's allergy business offers high-dose, hypoallergenic, standardized products for allergen immunotherapy of pollen and mite allergies. These allergoids have a special focus in Allergopharma's product portfolio and constitute a cornerstone in its integrated health approach for patients suffering from these conditions. For effective treatment, reliable diagnosis is key. Allergopharma offers a broad range of diagnostics in the field of allergies with more than 100 single allergens, providing physicians with the specific tools needed to identify the substances causing an allergy. In addition, Allergopharma provides individual allergen extracts on a named patient basis, which are needed to treat less frequent allergies. Personalized medicine has been a reality for Allergopharma for many years now. Products of Allergopharma are available in more than 20 countries worldwide.

Life Science

With one of the broadest product and technology portfolios in the industry, the purpose of the Life Science business sector is to solve the toughest problems in life science by collaborating with the global scientific community. Udit Batra has been the CEO of our Life Science business sector since 2014 and became a member of the Merck Executive Board in April 2016. In 2016, the Life Science business sector contributed 38% to Group sales and 34% to EBITDA pre exceptionals (excluding Corporate and Other).

We are a leading player in the attractive € 100 billion life science industry, serving more than one million global customers with the aim of advancing science faster to accelerate access to health for people everywhere. We offer innovative solutions for scientists and engineers at every stage. Our products and services are used in the research, development and manufacture of biotechnological and pharmaceutical drug therapies, as well as in research and application laboratories. In addition, our products and services also reach adjacent markets such as the food and beverage industry.

In November 2015, we acquired the Sigma-Aldrich Corporation, a leading life science company. This marked the largest acquisition in the history of Merck – and one of the largest in the industry. As a combined business, we are able to serve life science customers around the world with a highly attractive set of established brands such as Millipore, Sigma-Aldrich, Milli-Q®, SAFC, Supelco and BioReliance. Moreover, we have a highly efficient supply chain through which we can deliver standard products in 24 to 48 hours worldwide. In the laboratory and academia business, we offer customers an extensive and customized range of products across laboratory chemicals, biologics, and reagents.

Life Science operates in 66 countries around the world with the headquarters in Darmstadt, Germany and major hubs in Boston (Massachusetts), St. Louis (Missouri), Milwaukee (Wisconsin) and Molsheim in France. In July, we announced plans to build a new campus in Burlington, Massachusetts that will serve as a major hub for our North American life science business with an investment of US\$ 115 million. The 26,000 m² facility will include an M Lab™ Collaboration Center customer collaboration laboratory and training center as well as office space – a state-of-the-art, shared, exploratory environment where the company's scientists and engineers work together with customers.

The Life Science business sector generates recurring sales and stable, attractive cash flows in an industry that is characterized by stringent regulatory requirements. A highly diversified and loyal customer base additionally ensures a low risk profile. We benefit from a broad and relevant portfolio, a highly efficient supply chain including a superb eCommerce platform and global reach.

Our eCommerce platform sigmaaldrich.com allows customers in nearly every country to more easily find the exact products needed to advance their research. Currently, more than 70% of addressable legacy Merck Millipore products are available on sigmaaldrich.com. In 2016, we implemented a centralized initiative to manage all customer acquisition channels and scaled search advertising to include more than two million active keywords driving increased website traffic to the content customers are looking for, resulting in a streamlined customer experience.

The Life Science business sector is organized into three business areas which reflect customer segments. Research Solutions focuses on academia and pharmaceutical research institutions; Process Solutions markets products and services for the entire pharmaceutical production value chain, and Applied Solutions serves clinical and diagnostic testing laboratories, as well as the food and environmental industries.

To support these customer segments, our Strategic Marketing & Innovation (SMI) teams promote and deliver innovation tailored to our customers' needs. The SMI organizations are responsible for defining customer segment strategy, maintaining and innovating the product portfolio and communicating the business's strategic value propositions.

In addition, we have two commercial areas which are managed by region and customer segment to leverage regional and local expertise: one dedicated to the lab customers between Research and Applied and one dedicated to Process Solution customers. These areas are responsible for marketing, sales as well as customer and dealer relationships.

Research Solutions offers a broad and relevant portfolio of solutions that enable scientific discovery through complete partnership across the customer journey. This includes more than 200,000 products and services including molecular platforms, protein and pathway technologies, biochemicals, materials science, and cell culture workflow tools.

In Danvers, Massachusetts, we launched a transformation project at our current Mobius® manufacturing facility to improve capabilities within the facility. The project will include an additional 1,250 m² of cleanroom space to help meet the increasing market demand for single-use products.

In 2016, we introduced MILLIPLEX® MAP Human High sensitivity cytokine panel for faster and more cost-effective human cytokine assays. The new assay is the first 384-well kit for use with the Luminex FLEXMAP3D® platform and allows researchers with limited sample volumes who require high throughput to get more results, faster.

Our Process Solutions business offers a diverse range of products to pharmaceutical and biotechnology companies that enable customers to develop large- and small-molecule drugs safely, effectively and cost-efficiently. With the 2015 combination of Sigma-Aldrich and Merck Millipore, we now offer the broadest portfolio in the industry. The 15,000-plus products and services in Process Solutions include single-use manufacturing, filtration, chromatography and purification, virus reduction, pharma and biopharma raw materials, drug delivery compounds and engineering and validation services.

Our single-use solutions offer increased flexibility to biopharma customers since they eliminate time- and cost-intensive cleaning procedures. Moreover, these single-use solutions are compatible with various products, thus reducing investment costs for our customers. Launched in 2016, the new Mobius® products include a 1,000-liter single-use bioreactor with an industry-leading design, a 2,000-liter system for difficult-to-mix biopharma ingredients and a large-volume transport system for sterile and non-sterile liquids. These

products meet our customers' increasingly complex demands for user-friendly systems that allow them to focus on their science. We also deliver full end-to-end biopharma solutions by offering clients a full process line cGMP (current good manufacturing practices), from clone to commercial production.

In 2016, we expanded our industry-leading Emprove® risk assessment program to include selection of products for filtration and single-use processing. Rapid and easy access to risk assessment information is critical in an ever-changing regulatory landscape. The Emprove® program provides documentation and regulatory information on materials used in the manufacture of drug products and includes Millipore Express® filters, Pureflex® and Pureflex® Plus bags, Viresolve® Pro filtration devices and Durapore® filters.

In November 2016, we announced an € 80 million investment in a Life Science Center in Nantong, China, demonstrating a commitment to the industry's fast growth by providing a wide range of leading, innovative solutions for customers and partners in China. The facility will reinforce our leading position in inorganic salts for active pharmaceutical ingredients and excipients and cell culture media for the pharmaceutical, biopharma and healthcare markets in China as well as ready-to-use media for environmental and sterility testing.

The Applied Solutions business area focuses on diagnostic, testing and industrial customers and provides trusted products and comprehensive workflow solutions that streamline processes, lower costs and deliver consistent, reliable results. Our 62,000-plus products and services include analytical separation systems, reference materials, lab water instruments with consumables and services and microbiology and bio-monitoring testing materials.

Building on our commitment to improving workflows, we launched the Elix® high-throughput water purification system. Designed to operate at the heart of a central water purification solution, the Elix® system offers full connectivity, providing users real-time remote monitoring via computer, tablet or smartphone with access to all important water quality data. The product integrated seamlessly with existing systems and decreases energy and water consumption while maintaining water quality.

Our popular Guava® flow cytometers line was expanded with the addition of 532 nanometer lasers that increase the capabilities of the Guava® easyCyte instrument line to enable simultaneous detection of multiple fluorescent proteins. Since the discovery and isolation of the genes encoding proteins responsible for biological fluorescence, proteins have changed life science research. The new line enhances optical capability and flexibility and results in better optical configuration.

Performance Materials

Our entire specialty chemicals business is combined in our Performance Materials business sector. The portfolio includes high-tech chemicals for applications in fields such as consumer electronics, lighting, coatings, printing technology, paints, plastics, and cosmetics. Performance Materials comprises four business units: Display Materials, Integrated Circuit Materials, Pigments & Functional Materials, and Advanced Technologies.

Walter Galinat has been the CEO of the Performance Materials business sector since 2010. In April 2016 he was appointed to the Merck Executive Board. In 2016, the business sector's share of Group sales amounted to 17% and its share of EBITDA pre exceptionals (excluding Corporate and Other) was 23%. The EBITDA margin pre exceptionals was 44.1% of sales.

In 2016, we defended our position as the global market and technology leader for established liquid crystal technologies even though the growth in demand for liquid crystal displays (LCDs) was lower than expected. Large – mainly Asian – display manufacturers are among the customers of our Liquid Crystals (LC) business. The Display Materials business unit comprises the broadest product offering. We offer liquid crystal mixtures, for technologies such as PS-VA (polymer-stabilized vertical alignment) technology (primarily for televisions) and IPS (in-plane switching) technology (primarily for smartphones and tablets), photoresist materials and reactive mesogens. New developments such as energy-efficient UB-FFS (ultra-brightness fringe field switching) technology established themselves further in the market for smartphones and tablets.

The development of new application possibilities for liquid crystals was again an important focus of our LC 2021 strategic initiative in 2016. This primarily includes the development of liquid crystal window technology. In order to protect against solar radiation, these windows allow continuously variable switching from light to dark in just seconds and have high color neutrality compared with competitive technologies. A privacy version of the windows permits switching from transparent to opaque. To achieve faster market penetration of the new technology, Merck is investing around € 15 million in a production facility for liquid crystal window modules at a site in Veldhoven, the Netherlands. The manufacture of these switchable modules, which our customers can process into smart windows and glass façades, is to start at the end of 2017.

In 2016, our annual "Displaying Futures" symposium focused on future mobility. We want to use the Automotive Platform that we have developed to show the potential that Merck materials have in view of future trends. These include liquid crystals for free-form displays, liquid crystals for mobile antenna applications or adaptive lighting in headlights, OLEDs (organic light-emitting diodes), LEDs (light-emitting diodes), semiconducting materials in chips or functional pigments. To further young companies and researchers, in 2016 we presented the Displaying Futures Award for the first time. The prize, which is worth US\$ 50,000 and awarded for new ideas involving liquid crystal materials, went to three teams from the United States and the Netherlands.

Integrated Circuit Materials is our second-largest business unit and supplies products to manufacture integrated circuits and microelectronic systems, for antireflection coatings, and for the miniaturization of transistor structures. By integrating the two acquisitions, namely the SAFC Hitech business of Sigma-Aldrich and Ormet Circuits, we have ideally complemented our portfolio to include deposition materials and conductive pastes for semiconductor packaging. Advanced semiconductor manufacturers benefit from our cutting-edge material solutions for next-generation lithography, for example in directed self-assembly (DSA). We hold a leadership position in DSA technology thanks to our extensive expertise in polymer synthesis as well as many years of process and formulation experience. An important topic for the semiconductor industry is the development of increasingly powerful computer chips. This is being achieved by either making the structures on the chip even smaller (Moore's law) or combining different chips in the component or three-dimensional structures ("beyond Moore"). Merck offers various innovative products for both approaches. In addition to smartphones and servers, the main applications include sensors, for example for the automotive industry, and the Internet of Things. As an important partner to leading global electronics manufacturers, the business unit achieves more than 60% of its sales in Asia, generating around three-quarters of sales with products that are the leaders in their respective markets. In 2016, we also strengthened our positioning in the growth market of China.

The Pigments & Functional Materials business unit develops and markets a comprehensive product portfolio of decorative effect pigments and functional materials. The effect pigments are primarily used in automotive and industrial coatings, plastics, printing applications, and cosmetics in order to give products a unique shine. Functional materials include laser marking, conductive additives, applications for counterfeit protection as well as high-quality cosmetic active ingredients, for example for use in skin care, as well as sun protection and insect repellents. In 2016, we offered our customers various new products in all areas: For example, we launched the new Thermaval™ series of pearlescent pigments for high-temperature applications. They allow ceramic glazes to retain their brilliant colors and sparkle effect, also when used in ceramic glazes at cost-efficient single-firing temperatures. In 2016, our portfolio expansion and distribution activities also focused on collaborations – for example, with Agrimer of France to use marine cosmetic actives and with PolyOne of the United States to refine and market an innovative 3D plastics technology. Triggered by the Zika virus epidemic, we gained further market share with our insect repellent IR3535®, even in the existing market. The substance provides effective protection against mosquito bites and is also safe for pregnant women, who are at particular risk from the Zika virus. Merck received the prestigious European Frost & Sullivan Award for Product Leadership 2016 for its pioneering role in pigments used in high-quality automotive coatings. This recognizes the success achieved with the innovative Meoxal® and Xirallic® NXT lines.

The Advanced Technologies business unit invests particularly in future-oriented research and development in Performance Materials. A very good example of this are our materials for organic light-emitting diodes (OLEDs). The OLED materials business is one of our fastest-growing businesses. We opened the new production facility for OLED materials in Darmstadt in September as planned. After a 14-month construction period, high-purity OLED materials are being produced in the approximately 3,600 m² building. These are used not only in state-of-the-art displays, but also in modern lighting systems, such as in high-quality automotive tail lights. With a total investment of around € 30 million, this is one of the largest single investments Merck has made at the Darmstadt site in recent years. The plant makes it possible to significantly increase production capacity. We aim to be a leading supplier of OLED materials

by 2018. In order to meet the increasing demand and supply customers with a broad range of high-performance OLED materials, we have entered into a cooperation agreement with the Japanese company Idemitsu Kosan.

Quantum materials are another interesting new technology to improve displays. They enable ultra-bright displays with a notable expansion of the color gamut. In order to meet the growing demand for quantum materials, we entered into a licensing agreement with the Nanoco Group of the United Kingdom. The license allows Merck to immediately start marketing Nanoco's environmentally friendly cadmium-free quantum materials and to establish its own production facilities in the long term. In addition, we are also conducting research in quantum technology via the Israeli start-up Qlight Nanotech, which we acquired in 2015.

Objectives and Strategies

We want to advance technologies for a better life. Based on scientific research and in collaboration with partners, we are focusing on specialty products in healthcare, life science and performance materials.

General principles and Group strategy

General principles

Merck is a vibrant science and technology company. Our aim is to achieve technological progress that will improve life and make our customers and business associates more successful. This aspiration is embodied by values-based and economically sustainable corporate governance, has been anchored in our new brand promise since 2015, and steers the strategic development of the Group.

Our annual strategic planning process follows firmly defined principles. Our business portfolio must always be balanced so that it reflects an optimum mix of entrepreneurial opportunities and risks. We achieve this through our diversification into three complementary business sectors that make the company as a whole less dependent on economic cycles, as well as by expanding our presence in global growth markets. This exemplifies the long-term direction of our Group strategy. We want to continue the nearly 350-year-old success story of Merck into future generations and to achieve sustainable profitable growth. The partner structure of Merck KGaA with members of the Merck family as personally liable partners also contributes to this. It requires the Executive Board, whose members are also personally liable partners, to pay special attention to the long-term development of value.

For us, the principle of sustainability applies not only to economic aspects, but also encompasses corporate responsibility. We pursue three strategic spheres of activity: health, the environment and culture. The focus is always on the future viability of society and the competitiveness of our company. With our current and future product portfolio, we want to help solve global challenges, from urbanization to aging populations.

Group strategy

Over the past decade, Merck has transformed itself from a classic supplier of chemicals and pharmaceuticals into a global science and technology company. The main driver was the transformation of our business portfolio, particularly through the divestment of our Generics business (2007) and the acquisitions of Serono (2007), Millipore (2010), AZ Electronic Materials (2014), and Sigma-Aldrich (2015). In addition, we focused our businesses on innovation-driven and highly specialized products, extensively revamped our internal structures and processes, and expanded our presence in global growth markets.

Today, we hold leading positions in the respective markets of our three business sectors Healthcare, Life Science and Performance Materials, and are working to bolster and expand these. To this end, we are pursuing innovation-driven, organic growth. For instance, by 2022 we are targeting sales of around € 4 billion with new products. New medicines from the pharmaceutical pipeline are to contribute around € 2 billion, with Life Science and Performance Materials innovations each contributing around € 1 billion in sales.

Targeted acquisitions capable of meaningfully complementing or boosting our strengths remain a growth option. However, Merck continues to rule out major acquisitions of more than € 500 million as long as the debt level expressed as the ratio of net financial debt to EBITDA pre exceptionals is greater than 2, unless divestments could be used to finance them. By 2018, we aim to reduce our debt level to below 2 again.

Our Group strategy aims to resolutely continue the transformation of Merck into a specialized technology company and to position the company as a leading player in a changing market environment. For this purpose, we set up the Group Strategy & Transformation function in 2016. It unites the previously separately managed units Strategy, Innovation and Digitalization, and is designed to ensure the successful and timely implementation of core strategic projects. We have assigned these projects to three areas of key priority, namely "Performance", "People" and "Technology".

“Performance” encompasses all activities that create sustainable, profitable growth. To this end, we are closely aligning our businesses with the wishes and needs of customers and patients, not only through our products, but also best possible proximity. The basis for this is formed by efficient structures and processes as well as sustainable financial management. “Performance” is illustrated by the rapid and seamless integration of Sigma-Aldrich into our Life Science business as well as the realization of the associated synergies. We have progressed here faster than planned. In addition, previously unplanned top-line synergies are expected to contribute an additional € 20 million to earnings by the end of 2018. Consequently, total synergies from the Sigma-Aldrich acquisition will amount to € 280 million instead of originally € 260 million per year.

Merck’s growth strategy calls for a work culture that values diversity, promotes collaboration and responds flexibly to changing requirements. That’s because in today’s global knowledge society, qualified and motivated people are a crucial factor for entrepreneurial success, especially in a science and technology company like Merck. As a key priority area, “People” includes the further development of people management practices and creating an environment where innovation and creativity can thrive. We are paying particularly close attention to our leadership culture, talent pipeline and strengthening collaboration across national and departmental borders, for example through flexible work models or the use of a modern communication infrastructure.

The priority area “Technology” covers the closely interlinked areas of innovation and digitalization. Developing and marketing innovative products and services are at the forefront of our Group strategy and all the business strategies. Our objective is to foster innovations both within the businesses and between them as well as beyond existing businesses into areas in which we are not yet active.

In particular, we want to capture the opportunities that digitalization offers in order to create value for customers, business associates and patients. To us, digitalization means the digital integration of our entire value chain, the digitalization of our products, services and communication interfaces to customers as well as the development of new digital business models. This is supported by state-of-the-art methods to collect and analyze vast amounts of data (Big Data).

Additionally, we are working Group-wide to expand the physical and virtual infrastructure for technology-driven growth. The centerpiece will be formed by the Innovation Center in Darmstadt. Currently under construction, this 7,000 m² building is scheduled for completion by the end of 2017. Until its opening, our modular Innovation Center, which opened in 2015, offers a platform for the development of new technologies, for instance within the scope of our Accelerator program. Through this initiative and our expertise in science and technology, we support start-ups in transforming their visions into viable business models.

In 2016, we expanded our existing Biopharma venture fund to all three business sectors, increasing the total funding volume to € 300 million. Additionally, businesses beyond our current portfolio represent the fourth investment arm of the new Merck Ventures fund.

Capability initiatives

In 2013, Merck introduced four capability initiatives. They address topics that are of strategic importance to the performance of the entire company: The capability initiatives ONE Merck brand, ONE Talent Development, Rewards, and Performance Management, ONE Process Harmonization, and ONE Global Headquarters continue to drive important change or have started to evolve into regular activities. In October 2015, we introduced a fundamental revision of our brand design along with a simplified brand architecture, which we are currently implementing globally at all levels. In this context, we launched the digital brand campaign in 2016 called “Breakthroughs begin with curiosity” (curiosity.merckgroup.com), which puts the spotlight on scientific curiosity and passion for discovery as the driving forces of innovations.

Business strategies

Healthcare strategy

Global megatrends such as a growing world population and general increase in life expectancy are driving the demand for our healthcare products, namely biopharmaceuticals primarily for high unmet medical needs as well as consumer health brands that reflect the rising demand for preventive healthcare from an increasingly health-conscious society.

To meet these demands and appropriately respond to the dynamics of our healthcare markets, we have significantly transformed our Healthcare business sector in recent years. We are driving pipeline projects with the aim of bringing new groundbreaking medicines to patients, maximizing our existing portfolio and continuing our expansion in growth markets.

Our Healthcare business sector comprises the four businesses Biopharma, Consumer Health, Biosimilars, and Allergopharma. The diversity and profound medical expertise we have in these businesses are core strengths and key differentiators in the market. Within each business, we specialize in key therapeutic areas and specific diseases.

Our ambition in Healthcare is to become a global specialty innovator, to operate in therapeutic areas with significant unmet medical needs and to bring significant value to patients and consumers. Therefore, we invest heavily in research and development to discover new treatment options and improve existing ones. We are committed to working with our stakeholders and our partners to ensure that people can access the medicines they need to stay healthy and live longer.

In order to succeed in these areas, we seek sustainable ways to leverage our size, global set-up and innovation power. Here, striking the balance between innovation and operational excellence will be key. We are pursuing a comprehensive effort to further enhance our focus on customers. To boost customer intimacy, we are strengthening our relationships with healthcare professionals and building capabilities in digital, predictive and Big Data analytics.

The first pillar of our strategy is to reinforce our global footprint by developing our tailored portfolio to address unmet medical needs in all regions worldwide. While developed markets such as the United States, Japan and Europe are key strategic markets for our specialty innovation products, sales in growth markets such as China will be driven by our mature specialty, established biologics and broad general medicine portfolios. At the same time, it will be essential for us to continue to focus our efforts on growing in the United States in order to realize our ambition of being a truly global

leader. For example, with the co-promotion of Xalkori® with Pfizer, we have entered the United States oncology market, which is helping us to prepare for the future launch of avelumab, our anti-PD-L1 antibody.

The second pillar of our strategy is to develop specialty assets in early- and late-stage clinical development. Here, we are concentrating our efforts on oncology and immunology as well as ensuring we remain a relevant player in our core therapeutic areas. For example, we have made significant investments in R&D, especially in areas of unmet medical need, and refined our focus on mechanisms of action and molecules that are expected to lead to transformative innovations in cancer care, neurology and immunology. Our aim is to turn cancer patients into cancer survivors by being at the forefront of changing the future of cancer care. Further development programs for immunology and neurology include cladribine tablets, with a first-of-its-kind dosing regimen that serves as an important therapeutic option for patients with relapsing-remitting multiple sclerosis, and atacicept as a potential therapy of choice for lupus patients with high disease activity.

The third pillar of our strategy is innovation. Our aspiration is to develop high-quality, first-to-market and best-in-disease assets, and to build a portfolio in each of our chosen therapeutic areas. We have streamlined our pipeline and upgraded our innovation capabilities with strong investigational drug candidates. In order to maximize the impact of our R&D investments and increase our chances of success in discovering and developing new medical therapies, we focus our expertise on specific therapeutic areas and are exploiting synergies in disease mechanisms and biological pathways.

In this context, strategic collaborations are an integral part of delivering on our commitment to transforming the lives of patients living with serious unmet medical needs. We recognize the value of collaboration in the research and development of breakthrough therapies, as well as strengthening our current portfolio. Here, we focus on balancing the right blend of internal capabilities and external partnerships, building strong collaborations with other leaders in industry, including Pfizer and Genentech.

We are innovating beyond our pipeline projects with our Medical Devices and Services unit and our Fertility technologies. In addition to innovative therapeutic approaches, the way in which we engage with customers will be vital to achieving our objective of becoming a global specialty innovator.

Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017.

Life Science strategy

As a leading business in the € 100 billion life science industry, the purpose of the Life Science business sector is to solve the toughest problems in life science by collaborating with the global scientific community. To best meet the needs of our customers and accelerate innovation, the business areas responsible for life science innovation and product development are strategically organized around our customers. Research Solutions focuses on academia and pharmaceutical research institutions. Process Solutions markets products for the entire pharmaceutical production value chain. Applied Solutions serves clinical and diagnostic testing laboratories as well as the food and environmental industries. With an expanded portfolio of more than 300,000 products, most of which are available on our industry leading e-commerce platform sigmaaldrich.com, Life Science offers solutions, services and expertise across the entire biopharma value chain.

Our strategy focuses on three areas: driving our core business; realizing the planned synergies from the Merck Millipore and Sigma-Aldrich integration by the end of 2018, and establishing new pillars of growth.

To grow our portfolios, we are refreshing our operating model and go-to-market strategy. Additionally, we will strengthen key capabilities across Life Science by optimizing supply chain performance to align service levels in Research Solutions and Applied Solutions. In Process Solutions, we are showing strong business continuity and upgrading quality performance in specific areas. Our innovation capabilities remain critical for future growth and we will leverage intellectual property as a strategy in key areas such as gene editing. Information technology is a core capability for Life Science as we work to improve our eCommerce, digital marketing and analytics competences. Here we are building on and further expanding our leadership position from legacy Sigma-Aldrich.

We have completed the first of three years of integration and have made tremendous progress with all relevant roles in the new organization in place and consolidation of integration teams into respective business functions. The value of the integration is evident, with a significant increase in sales and the realization of synergies faster than anticipated through multiple geographic synergy initiatives, the eCommerce platform and complementary customer accounts. We continue to focus on basic process harmonization throughout the organization for employees and customer satisfaction.

Based on a broad assessment of the market and competitive landscape and key industry trends, we have identified six strategic initiatives to drive future growth. These include gene editing and cell therapy as well as end-to-end solutions, where we aim to be the partner of choice to accelerate product and drug development. We are focused on completing our end-to-end offering of early and late stage process development and facility design services for accelerating local drug production. In addition, we are creating a new connected lab ecosystem to solve laboratory pain points such as data collection, documentation and replenishment.

Performance Materials strategy

In the Performance Materials business sector we want to sustainably secure our market and technology leadership in display materials. In addition, we want to leverage our expertise in liquid crystals beyond the application field of displays. At the same time, we benefit from the trends in the semiconductor industry and will also continue to dominate the effect pigments market in applications for coatings.

Global demand for innovative display solutions grew further in recent years. We assume that increasing demand for high-quality consumer goods will come from an expanding middle class in growth markets also in the coming years. Therefore, we aim to continue to strengthen our position as the market and technology leader for liquid crystals. Key to this are new, sophisticated liquid crystal technologies. Our eco-friendly, resource-conserving and efficient liquid crystal technology SA-VA (self-aligned vertical alignment) for large-area displays is the next technology, with which the first products are expected on the market in 2017.

The Integrated Circuit Materials business unit supports the entire semiconductor industry with a portfolio of customized solutions. There are limits to further increasing the capacity of conventional silicon chips. At the same time, the costs, which for modern chips today already amount to more than 50% of manufacturing costs, are no longer declining at the same pace as before. This offers us the opportunity to develop novel materials that allow our customers to produce more powerful chips on the one hand, and to counteract rising costs with innovative processes on the other hand. Photolithography, deposition materials and dielectrics can increase semiconductor efficiency. Packaging materials are becoming increasingly important for the development of 3D chip variants. This is precisely where we have strengthened our portfolio through the acquisition of Ormet Circuits.

In the Pigments & Functional Materials business unit, we are further expanding our leading position in effect pigments for automotive coatings. We are continuing to defend our good market position in pearlescent pigments for plastics, printing and cosmetics applications. Here we are concentrating on high-quality products and on optimizing the supply chain. In functional materials, the focus of our growth strategy continues to be on niche applications in cosmetics (such as UV filters, insect repellents and anti-aging substances) as well as technical functional materials (such as laser marking and antistatic applications). Collaborations with external partners are particularly attractive here.

Our Advanced Technologies business unit aims to develop profitable future businesses – both for Performance Materials and for Merck's other business sectors. These also include the further development of OLED materials as well as organic photovoltaics. In 2016, we realigned our projects for future business fields to megatrends such as miniaturization and the Internet of Things.

Strategic initiatives

The two strategic initiatives OLED (organic light-emitting diodes) and LC 2021 are to significantly contribute to our future growth and continue to generate attractive margins. It is our declared goal to become the leading supplier of OLED materials. The commissioning of our new production plant for OLED materials in Darmstadt, which significantly increases our production capacity, has brought us an important step closer to this goal. The technology has the potential to change the future for displays and lighting. Intense colors, an especially deep black, thin structure, flexible use and low energy consumption are just some of the advantages offered by self-luminous OLED displays. OLED lighting applications score high with thin, filigree, lightweight lighting panels and a natural-appearing color spectrum. Under the umbrella of the LC 2021 strategic initiative, we are combining future applications of liquid crystals beyond classic displays. In six fields altogether, we are focusing on improved user experience on the one hand, and light and data management on the other hand. First and foremost, this comprises liquid crystal windows. In Veldhoven, the Netherlands, we are establishing our own production for modules used in sun protection and privacy control variants. It is scheduled to be commissioned at the end of 2017.

Strategic finance and dividend policy

We are pursuing a conservative financial policy characterized by the following aspects:

Financial flexibility and a conservative funding strategy

We ensure that we meet our obligations at all times and adhere to a conservative and proactive funding strategy that involves the use of various financial instruments.

We have diversified and profitable businesses as the basis for our strong and sustainable cash flow generation capacity. Moreover, we have several funding resources in place. A € 2 billion syndicated loan facility through to 2020 exists to cover any unexpected cash needs. The facility is a pure back-up credit facility and has not been drawn on so far. In addition, we can use a € 2 billion commercial paper program to issue short-term commercial paper with a maturity of up to one year.

Furthermore, we are using bilateral bank loan agreements with first-class banks in order to optimize the funding structure and cost. In this context, the bond market generally represents a key element. However, owing to our focus on deleveraging, no bonds were issued in 2016. In the past, Merck has mainly focused on bond issues in Europe. In addition, we issued hybrid bonds amounting to € 1.5 billion in 2014 and U.S. dollar bonds amounting to US\$ 4 billion in 2015 outside the Debt Issuance Program in order to broaden the funding basis and to address different investor groups.

Maintaining sustainable and reliable business relations with a core group of banks

We mainly work with a well-diversified, financially stable and reliable group of banks. Due to Merck's long-term-oriented business approach, bank relationships typically last for many years and are characterized by professionalism and trust. The banking group consists of banks with strong capabilities and expertise in various products and geographic regions. We regard these banks as strategic partners. Accordingly, we involve them in important financing transactions.

Strong investment grade rating

The rating of our creditworthiness by external rating agencies is an important indicator of the company's financial stability. A strong investment grade rating is an important cornerstone of Merck's financial policy, as it safeguards access to capital markets at attractive financial conditions. Merck currently has a Baa1 rating from Moody's and an A rating from Standard & Poor's (S&P), both with a stable outlook. In addition, the European rating agency Scope began covering our credit rating in 2016. The rating is A- with a stable outlook. Within the next two to three years, it is of utmost importance to us to sharply reduce our debt and to regain the ratings we had prior to the Sigma-Aldrich acquisition.

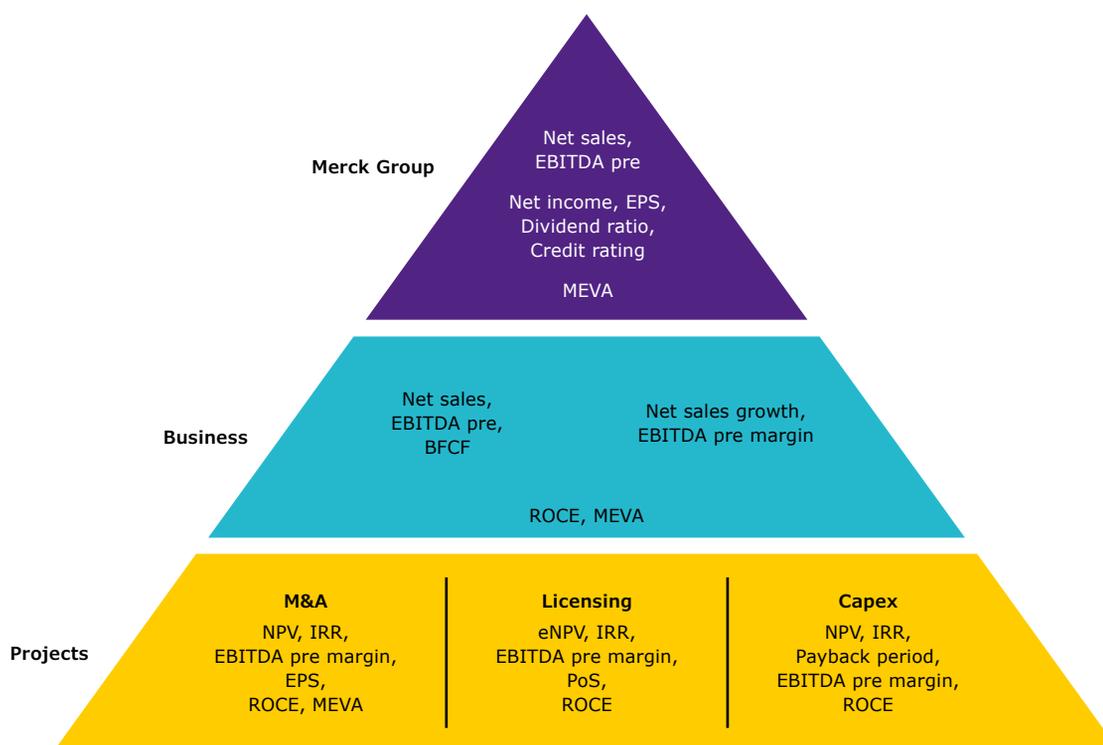
Dividend policy

We are pursuing a sustainable dividend policy. Provided that the economic environment develops in a stable manner, the current dividend represents the minimum level for future dividend proposals. The dividend policy is oriented towards the business development and earnings increase of the coming years. However, dividend growth could deviate, for example, within the scope of restructuring or in the event of significant global economic developments. We aim for a target corridor of 20% to 25% of EPS pre exceptionals.

Internal Management System

As a global company with a diverse portfolio of products and services, we use a comprehensive framework of indicators to manage performance. The most important KPI (key performance indicator) to measure performance is EBITDA pre exceptionals¹.

The Value Creation and Financial KPI Pyramid, which summarizes the important financial performance measures of the Merck Group, reflects the comprehensive framework of financial KPIs to steer the businesses and prioritize the allocation of cash resources. It consists of three managerial dimensions, namely Merck Group, Business and Projects, each of which require the use of different indicators.



Abbreviations

EBITDA pre = Earnings before interest, income tax, depreciation and amortization
 EPS = Earnings per share
 MEVA = Merck value added
 BFCF = Business free cash flow
 ROCE = Return on capital employed
 NPV = Net present value
 IRR = Internal rate of return
 eNPV = expected Net present value
 PoS = Probability of success
 M&A = Mergers and acquisitions

¹Financial indicator not defined by International Financial Reporting Standards (IFRS).

Key performance indicators of the Group and its businesses

The three key performance indicators net sales, EBITDA pre exceptionals¹, and business free cash flow¹ are the most important factors for assessing operational performance. Therefore, we refer to these KPIs in the Report on Economic Position, the Report on Risks and Opportunities, and in the Report on Expected Developments. As the most important indicators of financial business performance, the KPIs are key elements of our performance management system.

Net sales

Net sales are defined as the revenues from the sale of goods, services rendered to external customers, commission income and profit-sharing from collaborations, net of value added tax and after sales deductions such as rebates or discounts. Net sales are the main indicator of our business growth and therefore an important parameter of external as well as internal performance measurement. In addition, acquisition- and currency-adjusted sales are used for internal performance management.

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Net sales

€ million	2016	2015	Change	
			€ million	in %
Net sales	15,024	12,845	2,179	17.0%

EBITDA pre exceptionals

EBITDA pre exceptionals is the main performance indicator measuring ongoing operational profitability and is used internally and externally. To provide an alternative understanding of the underlying operational performance, it excludes from the operating result depreciation and amortization, impairment losses and reversals of impairment losses as well as exceptionals. The exceptionals are restricted to the following categories: integration costs, IT costs

for selected projects, restructuring costs, gains/losses on the divestment of business, acquisition costs, and other exceptionals. The classification of specific income and expenses as exceptionals follows clear rules and underlies strict governance at Group level. Within the scope of internal performance management, EBITDA pre allows for the necessary changes or restructuring without penalizing the performance of the operating business.

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Reconciliation EBIT to EBITDA pre exceptionals¹

€ million	2016	2015	Change	
			€ million	in %
Operating result (EBIT)¹	2,481	1,843	637	34.6%
Depreciation and amortization	1,805	1,383	422	30.5%
Impairment losses/reversals of impairment losses	129	128	2	1.2%
EBITDA¹	4,415	3,354	1,061	31.6%
Restructuring costs	22	48	-26	-54.0%
Integration costs/IT costs	193	78	116	>100.0%
Gains (-)/losses (+) on the divestment of businesses	-304	2	-305	>100.0%
Acquisition-related exceptionals	153	133	20	15.3%
Other exceptionals	11	16	-5	-32.7%
EBITDA pre exceptionals¹	4,490	3,630	861	23.7%

¹ Financial indicator not defined by International Financial Reporting Standards (IFRS).

Business free cash flow (BFCF)

Business free cash flow comprises the major cash-relevant items that the operating businesses can influence and are under their full control. It comprises EBITDA pre exceptionals less investments in property, plant and equipment, software, advance payments for

intangible assets, changes in inventories, trade accounts receivable as well as receivables from royalties and licenses. To manage working capital on a regional and local level, the businesses use the two indicators days sales outstanding and days in inventory.

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Business free cash flow¹

€ million	2016	2015	Change	
			€ million	in %
EBITDA pre exceptionals¹	4,490	3,630	861	23.7%
Investments in property, plant and equipment, software as well as advance payments for intangible assets	- 859	- 609	- 250	41.1%
Changes in inventories according to the consolidated balance sheet	3	- 950	953	>100.0%
Changes in trade accounts receivable as well as receivables from royalties and licenses according to the consolidated balance sheet	- 177	- 514	337	- 65.6%
Adjustment first-time consolidation of Sigma-Aldrich	- 149	1,210	- 1,359	>100.0%
Adjustment first-time consolidation of BioControl Systems	10	-	10	>100.0%
Business free cash flow¹	3,318	2,766	552	20.0%

¹ Financial indicator not defined by International Financial Reporting Standards (IFRS).

Investments and value management

Sustainable value creation is essential to secure the long-term success of the company. To optimize the allocation of financial resources, we use a defined set of parameters as criteria for the prioritization of investment opportunities and portfolio decisions.

Net present value

The main criterion for the prioritization of investment opportunities is net present value. It is based on the discounted cash flow method and is calculated as the sum of the discounted free cash flows over the projection period of a project. The weighted average cost of capital (WACC), representing the weighted average of the cost of equity and cost of debt, is used as the discount rate. Depending on the type and location of a project different mark-ups are applied to the WACC.

Internal rate of return (IRR)

The internal rate of return is a further important criterion for the assessment of acquisition projects and investments in property, plant and equipment. It is the discount rate that makes the present value of all future free cash flows equal to the initial investment or the purchase price of an acquisition. A project adds value if the internal rate of return is higher than the weighted cost of capital including mark-ups.

Return on capital employed (ROCE)

In addition to NPV and IRR, when looking at individual accounting periods, ROCE is an important metric for the assessment of investment projects. It is calculated as the operating result (EBIT) pre exceptionals divided by the sum of property, plant and equipment, intangible assets, trade accounts receivable and trade accounts payable, as well as inventories.

Payback period

An additional parameter to prioritize investments into property, plant and equipment is the payback period, which indicates the time in years after which an investment will generate positive net cash flow.

Merck value added (MEVA)

MEVA gives information about the financial value created in a period. Value is created when the return on capital employed (ROCE) of the company or the business is higher than the weighted average cost of capital (WACC). MEVA metrics provide us with a powerful tool to weigh investment and spending decisions against capital requirements and investors' expectations.

Capital market-related parameters

Net income, earnings per share (EPS) and earnings per share pre exceptionals (EPS pre)¹

Earnings per share are calculated by dividing profit after tax attributable to the shareholders of Merck KGaA (net income) by the weighted average number of theoretical shares outstanding. The use of a theoretical number of shares takes into account the fact that the general partner's capital is not represented by shares. To provide an alternative view, we also report earnings per share pre exceptionals, in other words adjusted for the effects of integration costs, IT costs for selected projects, restructuring costs, gains/losses on the divestment of businesses, acquisition costs and other exceptionals. Moreover, amortization of acquired intangible assets as well as impairment losses on property, plant and equipment and intangible assets are adjusted. The adjustment excludes impairment losses on intangible assets for acquired research and development (R&D) projects below a threshold value of € 50 million. Income tax is calculated on the basis of the company's underlying tax rate.

Credit rating

The rating of our credit worthiness by external agencies is an important indicator with respect to our ability to raise debt capital at attractive market conditions. The capital market makes use of the assessments published by independent rating agencies in order to assist debt providers in estimating the risks associated with a financial instrument. We are currently assessed by Moody's, Standard & Poor's (S&P) and Scope. The most important factor for the credit rating is the ability to repay debt, which is determined in particular by the ratio of operating cash flow to (net) financial debt.

Dividend ratio

With the aim of ensuring an attractive return to our shareholders, we are pursuing a reliable dividend policy with a target payout ratio based on EPS pre exceptionals (see definition above).

Other relevant/non-financial performance measures

Apart from the indicators of the financial performance of the businesses, non-financial measures also play an important role in furthering the success of the company. From a Group perspective, specifically innovations in the businesses as well as the attraction and retention of highly qualified employees are of central importance.

Innovation

Innovations are the foundation of our business and will also be the prerequisite for future success in changing markets. We are continuously working to develop new products and service innovations for patients and customers. Indicators for the degree of innovation are defined individually depending on the specifics of the respective businesses.

Talent retention

Employing a highly qualified and motivated workforce is the basis for achieving our ambitious business goals. Therefore, we put a strong focus on establishing the processes and the environment needed to attract and retain the right talent with the right capabilities at the right time. To measure the success of the related measures, we have implemented talent retention as an important non-financial indicator.

¹ Financial indicator not defined by International Financial Reporting Standards (IFRS).

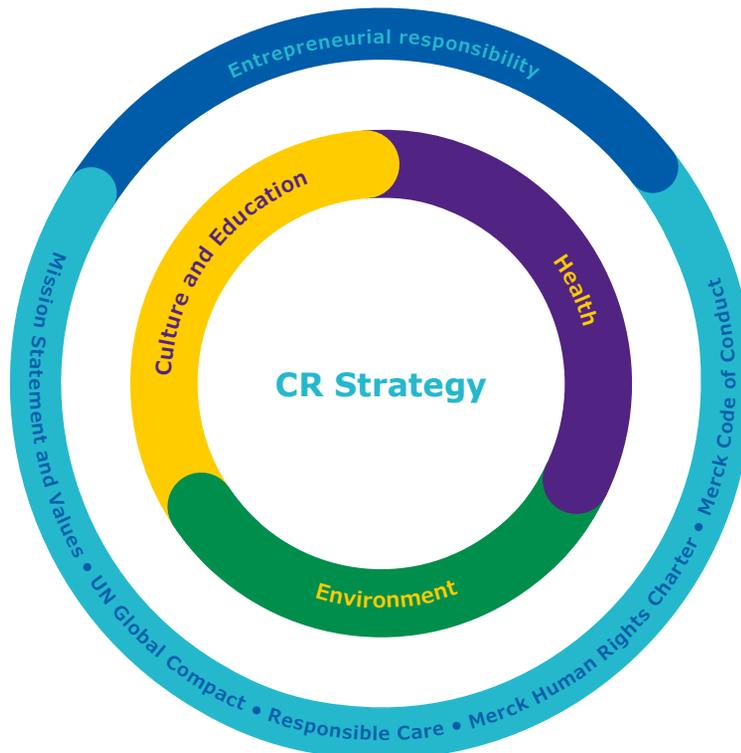
Corporate Responsibility

We take responsibility every day – and have been doing so for nearly 350 years. This commitment is codified in our corporate strategy and values. Responsible conduct with respect to employees, products, the environment, and society is a fundamental prerequisite for our business success.

Strategy and management

Our corporate responsibility (CR) activities are steered by our CR Committee, which consists of representatives from our business sectors and relevant Group functions. Belén Garijo, Executive Board Member and CEO Healthcare, became chairperson of the committee in June 2016.

Mankind is confronted with global societal challenges such as climate impact, resource scarcity and insufficient access to health in low- to middle-income countries. We believe that we can help resolve these global challenges through our innovative healthcare, life science and performance materials products, as well as through responsible governance. Responsible conduct means looking, listening and doing better. We respect the interests of our employees, customers, investors, and society, and work to minimize ethical, economic and social risks, thereby securing our success. This is an integral part of our corporate strategy, which in turn underpins our CR strategy, the basis for the responsible governance we live each and every day. In realizing our corporate responsibility, we focus our resources on those areas where we can have the greatest impact. We pursue three strategic spheres of activity: health, the environment as well as culture and education. The focus here is always on securing the future of society and our competitiveness.



Health: In low- to middle-income countries, many people lack access to high-quality health solutions. We are applying our expertise here and joining forces with strong partners to develop solutions for patients locally. Our fight against the worm disease schistosomiasis in Africa is a good example.

Environment: We are constantly working to improve the sustainability footprint of our products and are furthermore helping our customers achieve their own sustainability goals. One example is the development of new liquid crystal technologies through which our liquid crystals reduce the power consumption of smartphone and tablet displays.

Culture and education: Cultural offerings inspire people and expand their horizons. Research and development throughout the world thus benefit from creativity, ingenuity, and enthusiasm. Cultural inspiration also opens people up to new ideas. It favorably influences society's acceptance of science, technological progress and innovations. This is why we promote cultural initiatives and educational programs around the world.

We support relevant responsible governance initiatives. We are a member of the United Nations Global Compact and are committed to complying with the compact's principles regarding human rights, labor standards, environmental protection, and anti-corruption. Moreover, we also live our corporate responsibility through our commitment to follow the guidelines of the Responsible Care Global Charter, an initiative of the International Council of Chemical Associations (ICCA). Responsible Care aims to drive continuous improvement and achieve excellence in environmental, health and safety, and security performance in the chemical industry. We were among the first companies to sign the revised version of the Responsible Care Global Charter in 2014. Furthermore, we are also a member of the Chemie³ initiative in Germany, a collaboration between the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC), and the German Mining, Chemical and Energy Industrial Union (IG BCE). As part of this globally unique alliance, the partners want to make sustainability a core part of the chemical industry's guiding principles and to jointly drive the sector's position within the German economy as a key contributor to sustainable development.



To us, corporate responsibility means taking action and listening. The dialogue with our various stakeholder groups is therefore highly important to us. These stakeholders include employees, business associates, the Merck family, investors, regulatory agencies, and associations. We also engage in this continuous exchange to create transparency and clearly demonstrate how we live the Merck values.

Thanks to good performance with respect to responsible and sustainable entrepreneurial conduct, we were again included in the FTSE4Good index in 2016. To be included in this leading international sustainability index, a company must demonstrate socially conscientious, ecological and ethical conduct. In 2016, we also maintained our good standing in other major sustainability indices. For instance, we were again included in the STOXX Global ESG Leaders index, as well as the Euronext Vigeo Eurozone 120 index and the Ethibel Sustainability Index (ESI) Excellence Europe. In autumn 2016, among the German blue-chip companies included in the DAX, we achieved tenth place in the Good Company Ranking published by Kirchhoff Consult.

Strategic sphere of activity: Health

Access to Health (A2H) is one of our strategic priorities. Through our A2H approach, which spans all our businesses, we aim to help improve sustainable access to high-quality health solutions for underserved populations and communities in low- and middle-income countries. Since we realize that access is a complex and multifaceted challenge with no one-size-fits-all solution, our programs and initiatives are tailored to global, regional and local needs. We consider partnerships, collaboration and dialogue to be key instruments in delivering sustainable results.

During his presidency of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) from 2014 to the end of 2016, Stefan Oschmann, Chairman of the Executive Board and CEO, focused on the core topic of accelerating access to high-quality health solutions for people in low- to middle-income countries.

In November 2016, the Access to Medicine Foundation of the Netherlands recognized our efforts to improve access to health. In the 2016 Access to Medicine Index, Merck ranked fourth, moving up two places relative to 2014 and 13 places relative to 2010. Every two years, this index assesses the world's leading pharmaceutical companies with respect to their activities and initiatives to promote access to medicine in developing countries. The Access to Medicine Foundation praised us for our access goals, which have now been aligned with the Sustainable Development Goals (SDGs) of the United Nations. Through this ranking, the foundation also recognized our Access to Health (A2H) strategy, which is embedded in our core business and focuses on four areas known as the "4As": Availability, Affordability, Awareness, and Accessibility. The Access to Medicine Foundation also praised our numerous access initiatives.

Availability

Availability entails the research, development and refinement of health solutions that address unmet needs and are tailored to local environments. Together with our partners, we are working to fight widespread diseases in developing countries. One example is the Pediatric Praziquantel Consortium. Through this public-private partnership, we are working on a pediatric formulation of praziquantel to treat the worm disease schistosomiasis in children under the age of six. In 2016, the consortium launched a Phase II study in Ivory Coast. The objective of the study is to find the optimum dose of the new formulation. In October 2016, the consortium was furthermore awarded a prestigious research grant from the Japanese Global Health Innovation Technology Fund for the third time. Another example is our partnership with the Medicines for Malaria Venture, which seeks to develop new antimalarials. In 2016, we also launched a research collaboration with the University of Cape Town in South Africa to pursue the same objective. In addition to these efforts, our Healthcare and Life Science business sectors are currently developing a kit for malaria diagnosis based on the MUSE cell analysis system. This kit will detect and type the malaria pathogen as well as identify relevant immune cells in the event of a concurrent HIV infection. When used in insect repellents, our product IR3535® helps protect against infections transmitted by mosquito bites, such as malaria, yellow fever and the Zika virus. Products containing this active ingredient stand out due to their particularly good tolerability in young children and pregnant women.

Affordability

We seek to address affordability challenges through our efforts to provide assistance to those people who are unable to pay for the health solutions they need. To tackle these challenges, we have taken a pro-access approach through our intellectual property initiatives and are engaging in equitable pricing strategies. We provide transparent information about our patents and patent applications on publicly available databases. Moreover, we are a member of WIPO Re:Search, an open innovation platform sponsored by the World Intellectual Property Organization (WIPO). Through intellectual property and knowledge sharing, platform partners seek to accelerate early discovery for infectious diseases. In early 2016, our partnership with the University of Buea in Cameroon, which aims to repurpose compounds from our library to develop a treatment for onchocerciasis (also known as river blindness), received a research grant from the renowned Wellcome Trust of the United Kingdom. Furthermore, we are working with the World Health Organization (WHO) to combat the worm disease schistosomiasis in Africa. Through the Merck Praziquantel Donation program, we are donating Cesol® 600 tablets containing the active ingredient praziquantel to WHO. Since the start of this program, more than 100 million patients – primarily school-aged children – have been treated. In total, we have donated more than 500 million praziquantel tablets to WHO since 2007. As a founding member of the Global Schistosomiasis Alliance, we are helping to eliminate schistosomiasis worldwide.

Awareness

We help to raise awareness by empowering health workers, communities and patients with the appropriate tools, knowledge and skills to make informed decisions. For instance, we have been supporting the Developing Countries Vaccine Manufacturers Network (DCVMN) since 2012 in order to improve the safety and quality of biotech production. Through our Access Dialogues series, we are promoting discourse on access-to-health challenges with numerous public and private stakeholders. In 2016, the series focused on the supply chain. In India, we are working with various non-governmental organizations as well as the Indian Health and Family Ministry to support the Su-Swastha project, which is working to provide underserved rural populations with affordable health solutions and raise awareness on health issues. In 2016, the project had reached 26,129 people through 1,238 community meetings. The Global Pharma Health Fund (GPHF), a non-profit organization funded by Merck, works to combat counterfeit medicines in developing and emerging countries. To date, the GPHF has supplied more than 795 Minilabs at cost to detect counterfeit medicines in more than 90 countries. Furthermore, through our Capacity Advancement Program (CAP), we are working to raise awareness and further the prevention of non-communicable diseases such as diabetes and cancer, as well as to address the issue of infertility.

Accessibility

We promote initiatives to strengthen supply chains and to develop localized health solutions in order to deliver and reach out efficiently at the point of care. We support training and knowledge sharing with our manufacturing partners in Africa, Asia and Latin America with the aim of strengthening local manufacturing quality standards. In India, we are cooperating with the non-profit organization known as Narmada Samagra. Our River Ambulance transports health workers and provides healthcare solutions to local populations living in the remote region along the Narmada River. In early 2016, we donated a new boat to River Narmada Samagra so that even more people can be reached in the future. Additionally, we are funding a health center that serves around 150 patients a month in Jharkhand, a state in northeastern India.

Strategic sphere of activity: Environment

Through our products, we are helping overcome global challenges such as climate impact and resource scarcity. At the same time, we are also helping our customers to reduce the negative impacts of their own activities and to achieve their own sustainability goals.

Performance Materials: Investments to boost sustainability

In 2016, our Performance Materials business sector made several large investments. In August 2016, we announced plans to invest € 15 million in the construction of a production plant for liquid crystal window modules in Veldhoven, the Netherlands. In doing so, we are pursuing the goal of leveraging our market and tech-

nology leadership in liquid crystals beyond their use in energy-saving displays. The manufacture of the switchable glass modules is to begin at the end of 2017. According to initial measurement results, our smart windows can cut the energy use of air-conditioned buildings by up to 40% and replace conventional shading solutions. We are thus helping builders to save resources and costs. These windows can be manually or automatically controlled to darken and provide sun protection – and to do so in a variety of colors. This technology is made possible thanks to the special properties of our liquid crystals, which in smart windows are combined with customized dyes. When a low electric voltage is applied, the liquid crystals allow electromagnetic waves (i.e. light) to be either absorbed and blocked (dark state), or to pass through (transparent state). Another variant can control the transparency of liquid crystal windows. If people want more privacy, they can switch to privacy mode, which turns the glass opaque. In contrast to competitive technologies, our long-lasting licrivation® materials switch in seconds and have high color neutrality. Architects and builders can customize the desired color to suit the setting.

Furthermore, we opened a new OLED materials production plant at our Darmstadt site in September 2016. With a total investment of around € 30 million, this is one of the largest single investments we have made at the Darmstadt site in recent years. Organic light-emitting diodes (OLEDs) are semiconducting organic materials that luminesce when electric voltage is applied. They are particularly well suited for use in state-of-the-art displays and lighting. OLED displays provide brilliant colors and sharp images from any viewing angle and are highly energy-efficient. They are also thin and flexible, which enables entirely new shapes and opens up a broad spectrum of totally new applications.

For the semiconductor industry, we have developed a series of environmentally sustainable specialty chemicals and materials – including PFOS-free antireflective and photoresist coatings that contain no trace of dangerous chemicals.

In cooperation with our customers from the cosmetics industry, we are developing cosmetic formulations that meet strict sustainability criteria and align with the continuing trend towards more natural cosmetics. Many of our products meet the criteria defined by Ecocert, an independent organization representing high international standards for natural cosmetic raw materials.

Life Science: Reducing our customers' environmental impacts

Within our Life Science business sector, the Design for Sustainability (DfS) program aims to reduce environmental impacts of devices and instruments, also through customers' own use. Beginning with the concept stage, product teams identify potential environmental impacts in various product life cycle stages and opportunities to make improvements. A scorecard is used to assess product design in six focus categories: Materials, Energy & Emissions, Waste, Water, Packaging, as well as Usability & Innovation. As of December 31, 2016, we had achieved improvements in at least three of our self-defined sustainability criteria for 32% of our new Biomonitoring product developments and/or further developments.

In biopharmaceutical production, numerous products such as plastic bags and tubing are used only once and then disposed of. This is due, among other things, to the low risk of contamination posed by single-use products. Together with customers and recycling firms, our Life Science business sector is developing sustainable recycling programs. Our objective is to avoid incinerating the waste streams by offering recycling options so as to reduce the environmental impacts.

In addition, our Life Science researchers are developing innovative solutions in line with the “12 Principles of Green Chemistry” developed by chemists Paul T. Anastas and John C. Warner. The objective is to permit production that is as environmentally compatible as possible, and to minimize adverse effects on human health. Within the framework of Green Chemistry, researchers seek alternative, environmentally sustainable reaction media with higher reaction rates and lower reaction temperatures in order to make production more energy-efficient. With Dozn[®], we have developed a Web-based analysis tool for Green Chemistry. To date, we have used the matrix to evaluate more than 40 products and improve them afterwards.

In 2016, we launched Cyrene[™] onto the market. The solvent is based on renewable cellulose and is used, among other things, as an alternative to dimethylformamide. With Cyrene[™] we help our customers in the pharmaceutical and agrochemical industries to lower the environmental impact of their production processes and make them safer. Joint research work with the University of Strathclyde in Glasgow, United Kingdom, has proven the efficacy of Cyrene[™].

Strategic sphere of activity: Culture and Education

Cultural promotion is a core element of our commitment to society, building on our centuries-old tradition of supporting art as well as culture and education. After all, culture nurtures characteristics that are essential to our business activities as a high-tech company: creativity, enthusiasm for new discoveries, curiosity, and the courage to transcend boundaries. Our cultural initiatives focus on music, literature and education.

The Deutsche Philharmonie Merck

The Deutsche Philharmonie Merck is our musical ambassador. We consider classical music to be the universal language that brings people together; as such, it is an important part of our culture. The concerts of this professional ensemble are highly popular, with around 23,000 people attending them per year. They represent an integral part of the cultural life in the vicinity of our Group headquarters in Darmstadt. Special events for children and adolescents are intended to make classical music more accessible to young people, as do partnerships with schools like the orchestra workshop we have held once a year since 2010. In 2016, the Deutsche Philharmonie Merck celebrated its 50th anniversary and, among other activities, performed a joint concert at the Frankfurt Jahrhunderthalle with Einshoch6, a Munich-based hip-hop band.

Promoting literature

Literature can stimulate the imagination; it can alleviate fears and give courage. Literature can also address scientific issues, thus furthering a deeper understanding of science and research. Through our involvement, we want to help society better accept science and scientific progress. Furthermore, as an international company, we further writers who drive cultural exchange in our globalized world.

We grant and promote five literary prizes worldwide. Since 1964, we have been sponsoring the renowned Johann Heinrich Merck Award for Literary Critique and Essay, which is presented by the German Academy for Language and Poetry at its annual autumn conference. Worth € 20,000, this award went to writer and blogger Kathrin Passig in 2016. For 14 years, we have been sponsoring the Premio Letterario Merck in Italy. This award is worth € 10,000 and recognizes authors who build bridges between literature and science, thereby making them accessible to a wide audience. In 2016, the winners were Italian immunologist Alberto Mantovani and British writer, historian and naturalist Helen Macdonald. In India, Merck partners with the Goethe-Institut Calcutta to present the Merck Tagore Award. Worth 500,000 Indian rupees (around € 6,800), this literary prize is granted every two years to authors who have made a distinctive contribution to the cultural exchange between Germany and India. In 2016, psychoanalyst and writer Sudhir Kakar received the award. In Japan, we partner with the Goethe-Institut Tokyo to present the Merck Kakehashi Literature Prize. Worth a total of € 20,000, this award is granted every two years to contemporary works by German authors that are made accessible to a wider readership in Japan. In 2016, the prize went to writer Ilma Rakusa and her translator Fuminari Niimoto. In September 2016, Merck in Russia presented the first Merck Translation Award to Vladislava Agafonova (fiction), Kirill Levinson (non-fiction) and Alexandra Gorbova (children's literature). Each winner received € 4,000 in prize money.

Education

We view education as a key component of culture – and vice versa. Education can help us understand culture. But culture can also build a bridge to education; it can stimulate curiosity and nurture creativity. We therefore support educational projects at many of our sites by granting scholarships, for instance, or by sponsoring specific classes. To promote young scientists, Merck has hosted the renowned annual “Jugend forscht” science competition for the German federal state of Hesse every year since 1996. In partnership with the Technical University of Darmstadt, we inaugurated the Junior Biology Lab in autumn 2016.

The SPARK initiative was launched in early 2016. This volunteer program motivates employees from our Life Science business sector to share their knowledge with school students. In February and March 2016, 3,465 employees in 36 countries for the first time gave students exciting insights into the world of science, for example.

Responsibility for our products

The safety of our products is at the core of our corporate responsibility. When used properly, they must pose no risk to customers, patients, consumers, or the environment. Our goal is to ensure a positive benefit/risk profile for our products, which is why we regularly examine safety across their entire life cycle and continuously take steps to minimize risks. We provide patients, consumers and customers with extensive informational material so that they can use our products in a safe, responsible and proper manner.

Through our compliance policies for our Biopharma and Consumer Health businesses, we set standards for responsible marketing activities relating to our medicines. These aim to ensure that patients and healthcare professionals have access to the relevant information, and that patients receive effective treatment.

Safety of our chemical products

Numerous regulations are in place to ensure that chemicals pose no risk to humans or the environment. Compliance with these regulatory requirements is an important part of our work. Through our Group-wide Product Safety Chemicals policy, we have established global processes for defining, directing and implementing product safety, as well as the corresponding management structures. We incorporate all relevant national and international chemical regulations into our policies and guidelines and adhere to them. This includes the EU chemicals regulations REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (Classification, Labelling and Packaging of Substances and Mixtures, EU GHS). Furthermore, we are committed to transparency. For instance, in line with the Global Product Strategy, an international initiative of the chemical industry, we provide our customers with product safety summaries for hazardous materials.

We are working to register all our chemical substances in accordance with REACH. We successfully completed registration phase I in 2010 and registration phase II in 2013. The next step, in phase III, is for us to evaluate and register all substances produced or imported in quantities ranging from one to 100 metric tons annually by the beginning of June 2018. This process now also includes substances from Sigma-Aldrich and is fully on schedule.

Safety of our healthcare products

Patient and consumer safety has top priority in everything we do. During the entire life cycle of our medicines and consumer health products, we provide patients, consumers and physicians with up-to-date risk-benefit evaluations. To this end, company experts process safety-relevant information from various sources such as clinical trials, adverse reaction reports and scientific literature.

Ultimate responsibility for the safety of our biopharmaceuticals is borne by our Global Chief Medical Officer, with support from the Medical Safety and Ethics Board (MSEB). Our Global Drug Safety unit continuously monitors and evaluates the safety and risk-benefit ratio of our medicines worldwide (pharmacovigilance). For our Consumer Health products, this function is performed by the Global Product Safety unit. Overall responsibility for the safety of our over-the-counter products is borne by the Chief Medical Officer for the Consumer Health business, supported by the Safety & Labelling Committee (SLC).

For products in our Allergopharma business, we have developed comprehensive clinical efficacy and safety profiles that we continuously update. For the safety of our patients, we have established a global pharmacovigilance system that we are always working to enhance.

Quality of our products

Our goal is to provide customers and patients with high-quality brand-name products. Through our quality vision – “Quality is embedded in everything we do!” – we remind our employees of their responsibility across all business sectors, all Group functions and all levels of the company.

Supplier management

We source raw materials, packaging materials, technical products, components, and services from suppliers across more than 130 countries. Our basic expectations for suppliers and service providers include their compliance with fundamental environmental and social standards, which are primarily derived from the core labor standards of the ILO (International Labour Organisation), from the UN Global Compact, and from the Code of Conduct of the BME (German Federal Association for Materials Management, Purchasing and Logistics). Our Group Procurement Policy and Responsible Sourcing Principles define our procurement practices and are integrated into our general terms and conditions. They therefore constitute the foundation of every sourcing transaction and procedure. Due to the growing significance of emerging markets as sourcing markets for Merck, we have reinforced our efforts to ensure adherence to our supply chain standards. At the end of 2014, we joined the Together for Sustainability (TfS) chemical industry initiative. Since then, we have been utilizing the supplier assessment and audit results shared among all member companies, who in turn abide by all restrictions stipulated within competition law. Through TfS, we currently have access to assessments for more than 670 of our most important suppliers. Since 2015, we have initiated around 400 TfS assessments. In addition, we have initiated 26 TfS audits since 2014.

Responsibility for our employees

Employees are crucial to the success of a company. They therefore play a central role in our business endeavors. In accordance with the Merck values, we live a culture of mutual esteem and respect. We seek to further our entrepreneurial success by recruiting, developing and motivating the most suitable employees, which is why we focus our employee strategy on talent development, compensation, and performance management. We furthermore strive to foster diversity among our employees (more information can be found under “People at Merck”).

Responsibility for the environment

In the manufacture of our products, we seek to impact the environment as little as possible. This especially includes efficiently conserving resources such as energy, water and raw materials while also continuously reducing our emissions and waste.

Environmental management system

In our Corporate EHS Policy, we have defined our principles and strategies for environment, health and safety. This policy is implemented through internal guidelines and instruction manuals on compliant behavior in day-to-day operations, such as the Merck Group EHS Security and Quality Manual. At all our sites, local EHS managers are in charge of operational environmental protection measures. These employees continually receive training and obtain additional qualifications. Since our businesses are constantly changing, our environmental management system must also remain flexible and adaptable. For this reason, internal and external audits are conducted on a regular basis to determine whether the ISO 14001 requirements are still being met. In 2016, we obtained an ISO 14001 group certificate for our environmental management system for the eighth consecutive year. This certificate covers

57 sites. Seven sites belonging to the recently acquired company Sigma-Aldrich are already certified to ISO 14001. Our spending on environmental protection, health and safety efforts totaled € 189 million in 2016, which also includes investments made during the year.

Focus areas: Energy efficiency, greenhouse gas emissions, water

Climate impact and resource scarcity are key challenges facing society in the 21st century. As a responsible company, it is especially important for us to do our part. We have therefore set ourselves the goal of reducing total direct and indirect greenhouse gas emissions by 20% by 2020 (2006 baseline), irrespective of production growth. To achieve this goal, we have launched EDISON, a climate protection program that consolidates all our climate impact mitigation and energy efficiency activities. In 2017, we will continue investing in efforts to conserve energy and reduce greenhouse gas emissions. Through the approximately 270 EDISON projects initiated since 2012, we aim to annually save around 94 metric kilotons of CO₂ in the medium term. In 2016, we lowered our greenhouse gas emissions by around 10% relative to the 2006 baseline, despite growth in our operating business. Our Life Science business sector is playing a major role in our efforts. In 2014, process optimizations resulted in a two-thirds reduction in our process-related emissions at our facility in Jaffrey, New Hampshire (USA). In 2015, we initiated a project to further cut emissions that is scheduled to end in 2017. Other projects are being planned. In 2016, we also successfully completed measures to reduce greenhouse gas emissions and energy consumption at our site in Onahama, Japan. Because of its pigment production operations, this facility is one of the highest energy consumers of all Merck sites worldwide. For this reason, we switched the process steam generation for production to natural gas combustion, and the pigment kilns are now fired with natural gas. These changes are saving us roughly 3,200 metric tons of CO₂ emissions per year.

ENERGY CONSUMPTION¹

(in GWh)	2012	2013	2014	2015	2016
Total energy consumption	2,058	2,108	2,158	2,256	2,253
Direct energy consumption	1,187	1,286	1,354	1,451	1,443
Natural gas	1,070	1,157	1,212	1,212	1,272
Liquid fossil fuels	104	114	115	104	30
Biomass and self-generated renewable energy	13	15	27	135	141
Indirect energy consumption	871	822	804	805	810
Electricity	744	743	707	709	715
Steam, heat, cold	127	79	97	96	95

¹Portfolio-adjusted in accordance with the Greenhouse Gas Protocol.

CO₂EQ EMISSIONS (EQ = EQUIVALENTS)¹

Emissions in kt, Scope 1 and 2	2012	2013	2014	2015	2016
Total CO ₂ eq emissions	761	784	736	729	715
Direct CO ₂ eq emissions	379	417	390	393	386
Indirect CO ₂ eq emissions	382	367	346	336	329

¹Portfolio-adjusted in accordance with the Greenhouse Gas Protocol.

Energy management plays a key role in our efforts for sustainable energy efficiency and climate impact mitigation. Our production sites in Darmstadt and Gernsheim account for around 29% of our global energy consumption. In 2012, both of these facilities qualified for ISO 50001 – Energy Management System certificates, which were reaffirmed in 2016. Currently, 13 of our production sites have a certified energy management system. The results of the Carbon Disclosure Project likewise indicate that we are on the right path. In 2016, this independent non-profit organization ranked us among the top five companies in our industry in German-speaking countries. For the first time, we achieved the status of sector leader and, at fourth place, moved up two places relative to 2015. The Carbon Disclosure Project assesses companies in terms of their emissions reduction progress and climate impact reporting.

In addition to energy, we also focused on the topic of water in 2016. We systematically examined our sites to determine which ones have a high annual water consumption and are located in regions where water is scarce and thus an especially precious resource. At the beginning of 2016, we set the goal of implementing a sustainable water management system at sites with high consumption levels by 2020. At sites with relevant water use located in areas of high water stress, we are aiming to cut our water consumption by 10% by 2020 (2014 baseline).

Responsibility for society

We see ourselves as part of society – both at our individual sites and worldwide. Taking responsibility towards society is an integral part of our entrepreneurial approach. We believe that we can make an important contribution to society through our knowledge, our skills and our products.

Our social responsibility activities are primarily focused on those areas in which we have specific expertise stemming from our core businesses. We are thus engaged in health and environmental projects and furthermore support education, especially in the natural sciences. We provide disaster relief in emergency situations, particularly in those regions in which we operate.

Our subsidiaries are engaged in a wide variety of local projects. We have defined a general set of criteria for selecting projects, and the decisions concerning specific local projects are made by our subsidiaries. In 2016, we spent a total of € 43 million on community engagement activities. Our patient support programs, for instance the Erbitux® China Patients Assistance Program amounting to around € 153 million, are not taken into consideration here.

Research and Development

We conduct research and development (R&D) worldwide in order to develop new products and services designed to improve the quality of life of patients and to satisfy the needs of our customers. Further optimizing the relevance and efficiency of our research and development activities – either on our own or in cooperation with third parties – is one of our top priorities.

To address long-term health and technology trends in both established and growth markets, approximately 6,200 employees work for Merck researching innovations.

In 2016, Merck spent around € 2.0 billion on research and development, thus exceeding the previous year's level (2015: € 1.7 billion). This was due mainly to the intensified R&D activities of our Healthcare business sector. We focus on both in-house research and external collaborations, which enable us to increase the productivity of our research while simultaneously reducing financial outlay. The organizational set-up of our research and development activities reflects the structure of Merck with three business sectors.

Healthcare

Biopharma

Oncology

With regard to Erbitux®, we announced in April that the pivotal Chinese Phase III (TAILOR study) met its primary endpoint of significantly increasing progression-free survival (PFS) in patients with RAS wild-type metastatic colorectal cancer (mCRC) treated with Erbitux® (cetuximab) plus FOLFOX chemotherapy, compared with FOLFOX alone. Detailed data were presented from this first prospective study to evaluate an anti-EGFR antibody in first-line therapy of patients with RAS wild-type mCRC at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer in July in Barcelona. The study included 393 patients and showed that Erbitux® (cetuximab) plus FOLFOX statistically significantly improved outcomes compared to FOLFOX alone, including best overall response rate (61.1% vs. 39.5%), lowered the risk of disease progression by 31%, and decreased the risk of death by 24%. Progression-free survival was significantly improved by the combination of Erbitux® plus FOLFOX vs. FOLFOX alone (9.2 vs. 7.4 months), as was overall survival (20.7 vs. 17.8

months). These results reaffirm that Erbitux® plus FOLFOX is an effective treatment regimen for patients with RAS wild-type mCRC. As the first prospective trial evaluating Erbitux® in RAS wild-type patients, the TAILOR results show the importance of RAS biomarker testing in order to determine the appropriate targeted therapy for individual patients, based on their tumor's genetic make-up. The safety profile of Erbitux® in this trial was manageable and similar to that observed in other pivotal trials, with no unexpected safety findings. Based on these results, we are evaluating the most appropriate way to make Erbitux® available in China as a first-line treatment for patients with RAS wild-type mCRC as soon as possible.

In April we announced that a new liquid biopsy RAS biomarker test, which we are co-developing and commercializing with Sysmex Inostics, has been granted CE Mark approval. This test will now be made widely accessible for patients with metastatic colorectal cancer in Europe, Asia, Latin America and Australia. The testing technology, OncoBEAM® RAS CRC assay can be used to determine which patients would benefit from anti-epidermal growth factor receptor (anti-EGFR) therapies, such as Erbitux® (cetuximab). The liquid biopsy RAS biomarker test is a comprehensive 34-mutation panel that is based on the BEAMing (Beads, Emulsion, Amplification and Magnetics) technology. The test only requires a small blood sample (10 ml), rather than a tissue biopsy, to determine the mutation status of tumors. The test has the potential to provide mutation status results within days, which can help guide quicker treatment decisions. Merck and Sysmex Inostics originally entered into an agreement to co-develop and commercialize the liquid biopsy test in 2014.

In January we announced that we have signed a collaboration agreement with Biocartis for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with mCRC. The test will be developed on Biocartis' innovative, fully automated molecular diagnostics system, Idylla™, which is designed to offer accurate and reliable molecular information from virtually any biological sample. The Idylla™ system is a fully automated sample-to-result PCR-based (polymerase chain reaction) molecular diagnostics system. Whereas most of today's solutions only look for the most prevalent RAS mutations, the Idylla™ RAS test will be designed to detect an extended panel of RAS mutations. The new test will also provide a BRAF V600 mutation analysis directly integrated with the Idylla™ RAS test, to allow clinicians to evaluate BRAF and RAS mutation status simultaneously. Based on a 2 ml sample of blood plasma, the test aims to provide high sensitivity and ease-

of-use, requiring less than 2 minutes of hands-on time and a turn-around time of approximately 2 hours, enabling clinical decision-making in a timely manner. Merck and Biocartis plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centers across the world, excluding the United States, China and Japan. The test was subsequently submitted for a CE Mark.

In March we announced that we had entered into a collaboration focused on cancer metabolism with the European Molecular Biology Laboratory (EMBL), located in Heidelberg, Germany. The aim of the collaboration is to investigate mechanisms by which cancer cells generate energy and growth-enabling building blocks, which could ultimately deliver novel therapeutic targets, as well as biomarkers. The collaboration will make use of EMBL's capabilities in the area of metabolomics. During the three-year collaboration, EMBL will apply its unique expertise, combining modelling and bioinformatics with experimental approaches to investigate these metabolic pathways and shed light on their control mechanisms. EMBL will also utilize the cutting-edge equipment of its Genomics and Metabolomics Core Facilities to resolve the transcriptional and metabolic profiles of the samples for the study.

New research on Erbitux® and our pipeline compounds was presented at the Annual Meeting of the European Society for Medical Oncology (ESMO) in Copenhagen, Denmark, in October. Presentations focused on hard-to-treat cancers, and included study results for Erbitux® in mCRC and in squamous cell carcinoma of the head and neck (SCCHN), reaffirming Erbitux® as a standard-of-care therapy for mCRC patients with RAS wild-type tumors and patients with SCCHN. Preliminary study results were presented for our investigational product avelumab in bladder cancer, supporting its further development in this indication, as well as preliminary results from a combination study of avelumab with axitinib in renal cell carcinoma (RCC) that support the rationale to evaluate this combination in a Phase III pivotal study in RCC. Results on the investigational compound tepotinib, a highly selective c-Met kinase inhibitor, were presented on three posters, and included updates on the ongoing study program in c-Met-positive metastatic non-small cell lung cancer.

In September we commenced the clinical development of our investigational BTK inhibitor (M7583) in Oncology, with the start of our first Phase I clinical study of this compound. This first-in-human study in hematological malignancies represents a milestone of this program.

In June Merck announced jointly with Array BioPharma Inc. and Pierre Fabre the initiation of a randomized, global Phase III clinical trial of BRAF-mutant mCRC, investigating a new combination of Erbitux® plus encorafenib, with or without binimetinib. The trial, known as BEACON CRC (Binimetinib, Encorafenib And Cetuximab Combined to treat BRAF-mutant Colorectal Cancer) will assess the efficacy and safety of these two novel combinations in patients with BRAF-mutant tumors, compared with investigator's choice of Erbitux® plus irinotecan or Erbitux® plus FOLFIRI. Approximately 650 patients are expected to be enrolled by 2018 and, after a lead-

in period to assess the safety and tolerability of Erbitux® plus encorafenib (a BRAF inhibitor) and binimetinib (a MEK inhibitor), will be randomized to receive one of the two novel combinations, or the investigator's choice. The primary endpoint of the trial is overall survival. Key secondary endpoints include progression-free survival, objective response rate, duration of response, safety and tolerability. The trial will also assess health-related quality of life.

Our Grant for Oncology Innovation (GOI) initiative, which awards funds for pioneering independent research in oncology, was awarded on the occasion of the ESMO meeting on October 9. There were 405 applications from 49 countries for the 2016 award. Three research teams from Italy, New Zealand and Spain were selected to share the € 1 million grant to fund their research in the areas of breast cancer, colorectal cancer and lung cancer.

Immuno-Oncology

The investigational product avelumab is our most advanced clinical development program in immuno-oncology with eight Phase III studies sponsored by the Merck-Pfizer Alliance now underway in a variety of solid tumors.

On October 31, Merck and Pfizer Inc. announced that the European Medicines Agency (EMA) had validated for review Merck's Marketing Authorization Application (MAA) for avelumab, for the proposed indication of metastatic Merkel cell carcinoma (MCC). A rare and aggressive skin cancer, MCC impacts approximately 2,500 Europeans a year. Validation of the MAA confirms that submission is complete and begins the EMA's centralized review process. If approved, avelumab, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, could be the first approved treatment indicated for metastatic MCC in the EU. Patients with metastatic MCC face a very poor prognosis, with less than 20% surviving beyond five years. Avelumab received an Orphan Drug Designation (ODD) from the European Commission for MCC. The avelumab metastatic MCC MAA submission is supported by data from JAVELIN Merkel 200, a multicenter, single-arm, open-label, Phase II study of 88 patients with metastatic MCC whose disease had progressed after at least one chemotherapy treatment. The JAVELIN Merkel 200 study represents the largest data set of any anti-PD-L1/PD-1 antibody reported in this patient population. These data were recently published in the medical journal *Lancet Oncology*.

In November Merck and Pfizer Inc. announced that the U.S. Food and Drug Administration (FDA) had accepted for Priority Review the Biologics License Application (BLA) for avelumab in metastatic MCC. The application was submitted by EMD Serono, the biopharmaceutical business of Merck in the United States and Canada. This review relates to avelumab's proposed use in patients with metastatic MCC, based on tumor response results from the JAVELIN Merkel 200 trial. The FDA's Priority Review status reduces the review time from ten months to a goal of six months from the day of filing and is given to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists. The FDA previously granted avelumab Orphan Drug

Designation for MCC, as well as Fast Track and Breakthrough Therapy Designations for the treatment of patients with metastatic MCC whose disease has progressed after at least one previous chemotherapy regimen. Breakthrough Therapy Designation is intended to expedite the development and review of treatments for serious or life-threatening disease where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies for one or more endpoints.

The Merck and Pfizer alliance's presence at the 2016 American Society of Clinical Oncology (ASCO) annual meeting demonstrated how the collaboration between the two companies is making significant progress to rapidly accelerate the expansive, international development program (known as JAVELIN) for its investigational product avelumab. The program comprises 30 ongoing clinical programs assessing avelumab as monotherapy or combination therapy including nine pivotal studies, and approximately 4,000 patients across more than 15 tumor types. The data presented at ASCO 2016 contribute to the growing understanding of the potential role of avelumab in treating a broad range of cancers. In total 14 avelumab abstracts were presented (two oral presentations and 12 posters/poster discussions) across seven different cancer types.

One of the oral presentations concerned the results of JAVELIN Merkel 200 in metastatic MCC. The study showed a 31.8% objective response rate. There were 8 complete responses and 20 partial responses. Tumor responses were rapid, with 78.6% of patients (22 of 28) responding within 7 weeks of starting treatment, and durable, with 82.1% of patients (23 of 28) still responding at the time of analysis. Tumor responses were seen in patients regardless of the status of certain biomarkers (PD-L1 and Merkel cell polyomavirus). No unexpected safety signals were reported. Treatment-related adverse events (AEs) occurred in 62 patients (70.5%); the most common were fatigue (23.9%) and infusion-related reactions (17.0%), all of which were Grade 1 or 2 in severity. Grade 3 treatment-related AEs were reported in four patients (4.5%).

Other highlights of the avelumab clinical program reported at ASCO included the presentation of data in adrenocortical carcinoma, gastric/gastro-esophageal junction cancer, mesothelioma, non-small cell lung cancer, ovarian cancer and urothelial (bladder) cancer. Additionally, safety data were presented from 1,300 patients enrolled in the Phase Ib JAVELIN Solid Tumor trial, the largest Phase I trial investigating an anti-PD-L1 therapy.

In April Merck and Pfizer announced the initiation of a Phase III study of avelumab in an advanced renal cell carcinoma setting. The study, JAVELIN Renal 101, is a multicenter, international, randomized, open-label Phase III trial designed to evaluate the potential superiority, assessed by the progression-free survival, of first-line avelumab combined with INLYTA® (axitinib) compared with SUTENT (sunitinib malate) monotherapy in patients with unresectable, locally advanced or metastatic RCC with clear cell component.

It is the first pivotal trial investigating avelumab in combination with INLYTA® (axitinib), a tyrosine kinase inhibitor (TKI), in patients with previously untreated advanced RCC. Moreover, it is the only Phase III trial currently evaluating an anti-PD-L1 immunotherapy in combination with a vascular endothelial growth factor (VEGF)-receptor TKI in this setting.

In July we initiated a new Phase III study evaluating avelumab as a first-line treatment for ovarian cancer. This study, known as JAVELIN Ovarian 100, is an open-label, international, multi-center, randomized trial in treatment-naïve patients with locally advanced or metastatic ovarian cancer (Stage III or Stage IV). It is the first Phase III study evaluating the addition of an immune checkpoint inhibitor to standard-of-care in first-line treatment for this aggressive disease and aims to enroll approximately 950 patients, who will receive concurrent avelumab and chemotherapy, avelumab following chemotherapy, or chemotherapy alone.

In January Merck and Pfizer entered into an exclusive collaboration agreement with Syndax Pharmaceuticals, Inc. to evaluate avelumab in combination with Syndax's entinostat, an investigational oral small molecule that targets immune regulatory cells (myeloid-derived suppressor cells and regulatory T-cells), in patients with heavily pre-treated, recurrent ovarian cancer. Syndax will be responsible for conducting the Phase Ib/II clinical trial.

In March, Merck, Pfizer and Verastem announced that they had entered into an agreement to evaluate avelumab in combination with Verastem's VS-6063, an investigational focal adhesion kinase (FAK) inhibitor, in a Phase I/Ib trial in patients with advanced ovarian cancer.

In early 2017, we announced that we had entered into an agreement with the University of Texas MD Anderson Cancer Center for a three-year strategic collaboration aiming to more quickly advance the development of investigational therapies in four cancers – breast, colorectal, glioblastoma, and leukemia – through the study of biomarkers of response and resistance. We are therefore the first company to gain access to MD Anderson's Adaptive Patient-Orientated Longitudinal Learning and Optimization Platform (APOLLO) that standardizes the long-term collection of patients' medical history and data derived from tissue samples in order to better understand the biology of cancer and accelerate research-driven patient care.

Also in early January 2017, we reached a licensing agreement with Vertex Pharmaceuticals Inc., Boston, Massachusetts (USA), for the worldwide development and commercialization of four promising research and development programs that represent novel approaches to the treatment of cancer. As part of the agreement, we have licensed-in two clinical-stage programs targeting DNA damage and repair, along with two additional novel pre-clinical programs for which we will assume full responsibility for development and commercialization.

Neurology

The EMA accepted for review our MAA for the investigational product cladribine tablets for the treatment of relapsing-remitting multiple sclerosis (MS). This MAA submission includes data from three Phase III studies, CLARITY, CLARITY EXTENSION and ORACLE MS, and the Phase II ONWARD study. In these trials, cladribine tablets showed a significant reduction in relapse rates, risk of disability progression and development of new MS lesions, as detected by MRI, versus placebo in patients with relapsing-remitting MS. Together with interim long-term follow-up data from the prospective registry, PREMIERE, the new MAA includes follow-up data consisting of over 10,000 patient years of observation, with follow-up in some patients exceeding eight years.

At the European Academy of Neurology (EAN) meeting in Copenhagen in May 2016, new data and analyses were presented from clinical studies with cladribine tablets. Outcomes in patients from across the spectrum of relapsing MS were presented from the CLARITY, ORACLE-MS and ONWARD studies. The results of a re-analysis of the ORACLE-MS data in clinically isolated syndrome (CIS) were chosen by the organizers to be shown at the highlights session that showcases the most interesting data presented during the congress. This analysis showed efficacy of cladribine tablets in patients who would now be classified as having early multiple sclerosis according to the latest disease definitions, as well as an adverse event profile in line with previous experience. Further data investigating brain atrophy associated with cladribine tablet therapy vs placebo was presented from the CLARITY study. Final results on safety and tolerability were reported from the ONWARD study.

In September we presented clinical data for investigational cladribine tablets in two oral presentations at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in London. The findings, from the CLARITY and CLARITY EXTENSION trials and from the open-label maintenance period of the ORACLE-MS study, demonstrated durable efficacy of cladribine tablets in patients with MS along with an acceptable safety profile. Results from these studies confirmed that 20 days

of oral dosing over two years was effective in reducing the frequency of relapses and slowing disability progression for up to four years. The second oral presentation reported data from the open-label maintenance period of the Phase III ORACLE-MS study. ORACLE-MS showed that for patients with a first demyelinating event, treatment with investigational cladribine tablets significantly reduced the risk of progression to clinically definite MS compared with placebo. For the open-label portion of the study, patients who converted to clinically definite MS during the initial treatment period were switched to Rebif® therapy. The new data presented at ECTRIMS show that patients who had received investigational cladribine tablets in the initial treatment phase had lower annualized relapse rates over the maintenance period compared to those who had received placebo in the initial treatment phase.

On the occasion of the ECTRIMS meeting, we announced the recipients of the fourth annual Grant for Multiple Sclerosis Innovation (GMSI). In 2016, 260 proposals from 45 countries were submitted, representing innovative research projects taking place across the globe. Four international research teams from Canada, Germany, Israel, Qatar, Spain, and the United Kingdom were selected to share the € 1 million grant to support their research. The GMSI was launched in October 2012 with the aim of improving the understanding of MS for the ultimate benefit of patients living with the disease.

Concerning Rebif®, results of two non-interventional studies (REBIFLECT and REBISTART) were presented showing the positive effect of the RebiSmart™ injection device as well as nurse support for patient adherence to treatment, a key concern in patients requiring treatment for a chronic disease. In addition, a retrospective claims analysis was presented to investigate the reasons for treatment discontinuation over time.

As part of our portfolio prioritization efforts, and to allow us to focus on other ongoing projects in Neurology and Immunology, we returned the rights to the Phase II MS project ATX-MS-1467 to Apitope.

Immunology

In August the first patient in a Phase IIa clinical trial was dosed with our internally developed investigational product, the BTK inhibitor M2951. The study will evaluate the efficacy and safety of M2951 in subjects with rheumatoid arthritis on stable methotrexate therapy. A Phase II study with the same compound was initiated in December in systemic lupus erythematosus (SLE).

In November we announced the results of the ADDRESS II, Phase IIb, multicenter study on atacicept in patients with SLE, which were presented at the 2016 American College of Rheumatology/ Association of Rheumatology Health Professionals Annual Meeting in Washington, DC (USA). Patients on standard-of-care therapy (n=306) were randomized to weekly subcutaneous injections of atacicept (75 or 150 mg) or placebo for 24 weeks. The primary endpoint was the proportion of patients achieving a clinical response as defined by a composite SLE Responder Index (SRI)-4 at week 24. Secondary endpoints included SRI-6 response rate and time to severe flare, assessed by the SLEDAI flare index (SFI) or BILAG. Although the primary endpoint was not met in the overall study population, there was a trend favoring atacicept with statistical significance achieved in a pre-specified sensitivity analysis of the primary endpoint using treatment Day 1 as baseline (rather than screening visit); atacicept 75 mg (55.9%, adjusted odds ratio/OR 1.88, p=0.029) and 150 mg (55.8%, adjusted OR 1.96, p=0.020) compared with placebo (41.0%). BILAG A flares were significantly reduced compared to placebo with atacicept 75 mg (p=0.019), and severe SFI flare reduced with 150 mg (p=0.002). Additionally, analyses of a predefined subpopulation of patients with high disease activity demonstrated statistically significant treatment effects of atacicept when compared to placebo. SRI-6 response at week 24 was significantly greater with atacicept 150 mg compared with placebo. Both atacicept doses led to significant reductions in the incidence of severe flare versus placebo, BILAG A flare and SFI flare. Atacicept was also associated with increased serum complement C3 and C4, and decreased IgG, IgM, IgA, and anti-dsDNA antibodies over time. Treatment-emergent adverse event incidence was slightly higher with atacicept (150 mg, 80.8%; 75 mg, 81.4%) than placebo (71.0%), however, the risks of serious adverse events or serious/severe infections were not increased with atacicept versus placebo, and there were no deaths. The safety findings were comparable for the high disease activity subpopulation.

Fertility

In July we announced our continued support for the advancement of medical science in the field of fertility through the Grant for Fertility Innovation (GFI) program by awarding grants totaling € 1.5 million in 2016/17. The announcement was made on the occasion of the 32nd annual meeting of European Society of Human Reproduction and Embryology (ESHRE) in Helsinki, Finland. Launched in 2009, the GFI is dedicated to transforming innovative translational fertility research projects into concrete health solutions to improve the outcomes of assisted reproductive technologies. In 2016, six winning projects from China, Hong Kong, Ireland, the United States, and Italy (two teams) were selected from 112 global proposals with the overall goal of improving the chances of conceiving.

In October we launched two innovative fertility technologies, Gavi™ oocyte protocol and Geri™ medium. Both products help to improve key steps of assisted reproductive treatment (ART) – an area where laboratory technologies play a vital role for treatment success.

The launches represent the seventh and eighth product launch in 18 months for the Fertility Technologies unit at Merck, demonstrating the company's healthcare strategy to deliver innovation through best-in-class assets. Gavi™ enables clinics to preserve human egg cells, also called oocytes, and embryos at the main stages of ART, while Geri™ medium supports undisturbed cultivation of embryos. Preserving oocytes or embryos for future in vitro fertilization and embryo transfers by cooling them to deep sub-zero degrees is a key step in the laboratory. Gavi™ is the world's first automated instrument for this preservation technique, also called vitrification. With its latest product innovation, Gavi™ provides clinicians with added flexibility when taking important treatment decisions with and for their patients. Geri™ medium was developed to help improve another critical factor for successful treatment, embryo cultivation. After fertilization, the embryo needs to grow and develop before it is transferred into a woman's womb. With the single-step culture medium, Merck now provides a way to support undisturbed incubation and optimal embryo development. Both products are being commercialized as part of the partnership between Merck and Australian company Genea Biomedx.

We announced in mid-November that we had launched two new innovative fertility technologies, Gidget™ and Geri™+, to extend our innovative portfolio to support all steps performed by fertility laboratories during ART, where technologies play a vital role for treatment success. Gidget™ is designed as an easy-to-use witnessing and tracking system to reduce the potential for error and improve lab workflows, and Geri™+ is the basis to combine the Geri™ embryo incubator and the innovative Eeva® algorithm. Both new products underline Merck's healthcare strategy to provide innovation to patients/customers through best-in-class products. Gidget™ and Geri™+ stem from the ARTinnovations development hub, which we formed in collaboration with Genea Biomedx, Australia. ARTinnovations is an incubator for ideas and innovations for fertility treatment and technologies. It combines the commitment and know-how of both partners to develop ideas that can take root and grow into better outcomes for patients.

Integrating bright- and dark-field imaging, the Geri™+ incubator allows for combination with the Eeva® software and any Geri Assess version. Geri+ becomes a multifunctional incubator, which gives embryologists a multitude of possibilities around embryo analytics. It brings together the benefits of undisturbed incubation, while complying with the high control and safety standards of the Geri™ incubator and the analytics of the Eeva® software, the first automated algorithm clinically shown to improve embryo assessment.

Gidget™ is a hand-held device for the IVF laboratory that lets the embryologist focus on the science by eliminating any chance of mismatching, and includes unique tracking and workflow features. It provides electronic witnessing, lab workflow management and support for traceability and audit reporting.

General Medicine & Endocrinology

In mid-October we announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA has issued a positive opinion recommending extension of the label for all metformin-containing products, including the Glucophage® product portfolio and Glucovance®, for the treatment of type 2 diabetes patients. The label change will lift the former contraindication for stable renal failure CKD stage 3. The maximum daily metformin dose will be 2,000 mg/day in CKD stage 3a (GFR = 45–59 ml/min) and 1,000 mg/day in CKD stage 3b (GFR = 30–44 ml/min), allowing a large additional group of type 2 diabetes patients with reduced kidney function to benefit from the treatment. In a recent analysis in CPRD, a UK medical record database, 32.7% of all diabetic patients had CKD stage 3.

Following a routine evaluation of the safety of metformin medicines, it was found that based on scientific evidence and clinical guidelines, patients with moderate renal failure may stand to benefit from treatment with metformin, and that the contraindication may therefore no longer be justified. Based on this evidence, the EMA issued an Article 31 referral requesting a cumulative review of the benefit and risk in this patient group across all metformin selling companies in the European Union. Leveraging around 60 years of experience in market as the metformin originator, Merck supported the EMA request by providing a comprehensive analysis of all available clinical data on the efficacy and safety of metformin in patients with CKD stage 3. This was balanced against a cumulative analysis of all case reports Merck has received for lactic acidosis, the very rare risk associated with metformin accumulation due to acute or severe renal failure. The EMA reviewed the data submitted by all companies, and as a result, the CHMP issued a positive opinion on lifting the contraindication for treatment of type 2 diabetes patients with renal impairment CKD stage 3.

In September we announced the recipients of the Grant for Growth Innovation (GGI) for 2016. The awards are intended to advance understanding in the field of human growth disorders. This year's winners were announced at an award presentation meeting held on the occasion of the 55th European Society for Pediatric Endocrinology (ESPE) Meeting in Paris, France. Thirty-eight applications were received from 20 countries and following a rigorous selection process, three awards were made to innovative projects from Australia, Brazil and Italy.

BIOPHARMA PIPELINE

as of December 31, 2016

Therapeutic area	Indication	Status
Compound		
Neurology		
Cladribine tablets (lymphocyte-targeting agent)	Relapsing-remitting multiple sclerosis	Registration ¹
Oncology		
Tepotinib (c-Met kinase inhibitor)	Non-small cell lung cancer	Phase II
Tepotinib (c-Met kinase inhibitor)	Hepatocellular cancer	Phase II
Tepotinib (c-Met kinase inhibitor)	Solid tumors	Phase I
M2698 (p70S6K and Akt inhibitor)	Solid tumors	Phase I
M3814 (DNA-PK inhibitor)	Solid tumors	Phase I
BeiGene-283 (BRAF inhibitor)	Solid tumors	Phase I
M7583 (BTK inhibitor)	Hematological malignancies	Phase I
Immuno-Oncology		
Avelumab (anti-PD-L1 mAb)	Merkel cell carcinoma	Registration ²
Avelumab (anti-PD-L1 mAb)	Non-small cell lung cancer, 1 st line	Phase III
Avelumab (anti-PD-L1 mAb)	Non-small cell lung cancer, 2 nd line	Phase III
Avelumab (anti-PD-L1 mAb)	Gastric cancer, 1 st line	Phase III
Avelumab (anti-PD-L1 mAb)	Gastric cancer, 3 rd line	Phase III
Avelumab (anti-PD-L1 mAb)	Bladder cancer, 1 st line	Phase III
Avelumab (anti-PD-L1 mAb)	Ovarian cancer platinum-resistant/ -refractory	Phase III
Avelumab (anti-PD-L1 mAb)	Ovarian cancer, 1 st line	Phase III
Avelumab (anti-PD-L1 mAb)	Renal cell cancer, 1 st line	Phase III
Avelumab (anti-PD-L1 mAb)	Locally advanced head and neck cancer	Phase III
Avelumab (anti-PD-L1 mAb)	Solid tumors	Phase I
Avelumab (anti-PD-L1 mAb)	Hematological malignancies	Phase I
M9241 (NHS-IL12, cancer immunotherapy)	Solid tumors	Phase I ³
M7824 (anti-PD-L1/TGFbeta trap)	Solid tumors	Phase I
Immunology		
Sprifermin (fibroblast growth factor 18)	Osteoarthritis	Phase II
Atacicept (anti-BLys/anti-APRIL fusion protein)	Systemic lupus erythematosus	Phase II
M2951 (BTK inhibitor)	Rheumatoid arthritis	Phase II
M2951 (BTK inhibitor)	Systemic lupus erythematosus	Phase I
M1095 (ALX-0761, anti-IL-17A/F nanobody)	Psoriasis	Phase I
Abituzumab (anti-CD51 mAb)	Systemic sclerosis with interstitial lung disease	Phase II
Biosimilars		
MSB 11022 (proposed biosimilar of adalimumab)	Chronic plaque psoriasis	Phase III

¹As announced on July 18, 2016, the European Medicines Agency (EMA) has accepted for review the Marketing Authorization Application (MAA) of cladribine tablets for the treatment of relapsing-remitting multiple sclerosis (MS).

²As announced on October 31, 2016, the European Medicines Agency (EMA) has validated for review Merck's Marketing Authorization Application (MAA) for avelumab for the proposed indication of metastatic Merkel cell carcinoma (MCC). Additionally, as announced on November 29, 2016, the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the Biologics License Application (BLA) for avelumab in this indication.

³Sponsored by the National Cancer Institute (USA).

More information on the ongoing clinical trials can be found at www.clinicaltrials.gov
 Pipeline products are under clinical investigation and have not been proven to be safe and effective.
 There is no guarantee any product will be approved in the sought-after indication.

Akt Protein kinase B
 APRIL Proliferation-inducing ligand
 BLyS B-lymphocyte stimulator
 BTK Bruton's Tyrosine Kinase
 IL Interleukin
 mAb Monoclonal antibody
 PD-L1 Programmed cell death ligand 1
 PK Protein kinase

Consumer Health

Our Consumer Health business develops and sells over-the-counter medicines and food supplements in Europe, in particular in France, Germany and the United Kingdom, and in growth markets in Latin America, the Middle East and Africa, and Southeast Asia. The focus of our research and development activities is on the continuous improvement of existing formulations as well as on the development of new products and line extensions. We are following a consumer-centric innovation approach based on intensive market research across all our key markets. Since 2014, we have been establishing cooperation agreements with independent third-party research facilities to leverage their specific capabilities and expertise for the development of new products that meet the specific needs of our consumers.

Biosimilars

In March, we announced the initiation of a global Phase III clinical study in patients with chronic plaque psoriasis, of MSB11022, a proposed biosimilar of adalimumab, a recombinant human monoclonal antibody that binds specifically to tumor necrosis factor-alpha (TNF- α). The AURIEL-Psoriasis (PsO) study is a randomized, double-blind, active-controlled trial evaluating the efficacy, safety and immunogenicity of Merck's adalimumab biosimilar candidate MSB11022 compared with Humira® (adalimumab) in patients with moderate to severe chronic plaque psoriasis. Humira® is marketed globally by AbbVie, Inc., USA. The study is expected to recruit approximately 400 patients across Europe, Asia as well as North and Central America.

Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017.

Allergopharma

Allergopharma, our allergy business, is one of the leading manufacturers of diagnostics and prescription drugs for allergen immunotherapy. With its own research department and in cooperation with research institutes and other partners, we are helping develop a better understanding of the immunological mechanism that underlies the development of allergies and are actively working on the next generation of drugs for allergen immunotherapy.

Life Science

Innovation is at the core of the value that we deliver to our customers. Our Life Science business sector has approximately 1,500 employees working in various R&D functions around the world. These teams collaborate closely with our customers to solve the toughest problems in life science by translating ideas into product innovations. To do so, we invest significantly in R&D.

2016 marked a year of diverse innovation activities that are contributing to our promise of accelerating access to health for people everywhere. We aim to:

- Improve and expand our portfolio
- Invest in new and disruptive technologies for the long term
- Partner with the global scientific community
- Meet customer needs

Improving and expanding the portfolio

We launched innovations across all segments of our portfolio throughout the course of 2016. In Research Solutions, we launched the CellASIC® ONIX2 Microfluidic System for advanced live cell imaging. The system converts laboratory microscopes into powerful tools for live cell imaging to more effectively perform in-depth analysis of cellular mechanisms and behaviors in a live environment.

In Process Solutions, we updated our bioreactor system, critical for drug development, with the new Mobius® products that include a 1,000-liter single-use bioreactor, Mobius® 1000, and a 2,000-liter mixing system, Mobius® Power MIX 2000. We also expanded our state-of-the-art single-use current Good Manufacturing Practice (cGMP) facility, in France, with the addition of Mobius® 2,000-liter single-use bioreactor to facilitate accelerated drug development and delivery via continued innovation and technical expertise by offering customers a complete end-to-end solution.

The latest addition to our comprehensive excipients portfolio is Parteck® MXP, a polyvinyl alcohol-based excipient that enhances solubility of a wide range of active pharmaceutical ingredients (APIs) with poor bioavailability. The product allows customers to address solubility challenges that otherwise might have prevented promising and potentially life-changing candidates from progressing through the pipeline. As part of this portfolio, Parteck® SRP 80 was awarded for excellence in innovation by the global organization CPhI, as a functional direct compressible excipient designed for oral sustained-release formulations. It is fully synthetic for batch-to-batch and performance consistency and enhances the bioavailability of actives.

As an industry leader in filtration, we enhanced our portfolio with Viresolve® Pro Shield H, which effectively improves aggregate removal and reduces the required virus filtration area needed to process feed streams, while delivering the same high level of virus clearance customers expect. The new Viresolve® Pro Shield H is designed for use as a prefilter with Viresolve® Pro Device for more robust, cost-economic viral clearance.

In Applied Solutions we expanded our portfolio of Cerilliant® certified reference materials for applied diagnostics and testing. We introduced nine new Certified Spiking Solutions® that leverage the latest research and techniques from around the world for accurate and reliable starting materials.

Since introducing the first water filtration device in 1974, we have set the standard for reliability and convenience in sterility testing. Our new Steritest™ Symbio Pump accessories address testing challenges in various laboratory settings and enhance safety and convenience during sample handling, filtration and waste management as well as canister transport, incubation and reading.

Investing in new and disruptive technologies for the long term

Advancements in gene editing tools like CRISPR are helping to accelerate discovery and manufacturing of new treatments for difficult-to-treat conditions. We produce gene editing tools and cell lines for both faster, better drug discovery and faster, better biomanufacturing of gene-modified cell therapies. Our innovations in 2016 showcased our commitment to empowering scientists and researchers with the solutions they need to develop new tools that can improve health.

In March 2016, we announced that our CRISPR Epigenetic Activator was named to *The Scientist's* Top 10 Innovation list. The system enables the life science community to explore advanced regulatory aspects of gene expression by allowing epigenetic modification of genetic loci at both close and distal locations to a gene of interest.

Following this accomplishment, in May we announced the expansion of our Carlsbad, California facility to meet the growing demand for viral and gene therapy products. The expansion builds on our industry-leading offerings in the manufacturing and testing of innovative and complex products and will seamlessly support customers from clinical to commercial scales. The expansion incorporates single-use equipment in a flexible, scalable format for clinical and commercial bulk drug production.

In September, we launched new gene editing technology to modify CHO cell lines to be resistant to minute virus of mice (MVM), a common contamination threat that remains despite the shift to chemically defined, animal-component-free manufacturing processes. The Centinel™ technology targets genes which play a role in MVM susceptibility and exemplifies how we are addressing some of the industry's most complex challenges through the unique combination of experience and technologies.

We also introduced the Sanger Arrayed lentiviral CRISPR libraries, the first human and mouse arrayed lentiviral CRISPR libraries for knocking out and screening gene function. Recognized by *R&D Magazine* as a top 100 R&D innovation, the library allows discovery of genes involved in drug resistance, human disease and a wide variety of biological processes.

Partnering with the global scientific community

We entered into a research agreement with the International Vaccine Institute of Seoul, Korea, to help develop next-generation purification processes. Through this partnership, we are improving the manufacturing process to deliver greater yield, allowing higher recovery and purer vaccines. We will help create a more modern, scalable and robust manufacturing process so as to increase access to life-saving vaccines in developing countries.

Our customers face many challenges when it comes to the development, manufacture and delivery of vaccines. As a business committed to sharing our technological expertise in this area, we joined the DiViNe project, a European consortium of six companies working to create an integrated, cost-efficient purification program specifically tailored for vaccines that achieve higher yields while preserving product integrity. As an industry leader in chromatography, we specifically focus on simplifying the process of vaccine purification that typically relies on affinity chromatography, a method of capturing antibodies.

In addition, a signed collaboration agreement with Evotec International GmbH, Hamburg, aims to accelerate discovery workflows and eliminate the need for resource-intensive in-house assay development and screening. The collaboration allows customers to select a customized set of CRISPR and shRNA libraries and then leverage Evotec's extensive capabilities in phenotypic screening within primary and induced pluripotent stem cells and in vivo disease models. Customers can more rapidly and efficiently explore disease pathways and identify new targets.

In December, we expanded our distribution alliance with various companies of the Roche Group, Switzerland, to be the exclusive supplier of novel enzymes for polymerase chain reaction (PCR) and quantitative real-time PCR enzyme products of Kapa Biosystems, a company owned by Roche. The alliance extension gives our customers greater access to novel products through our world-class distribution channel. The agreement is a growth driver for our Life Science business sector, which offers premier brand tools for genomics, proteomics and cell analysis.

Meeting customer needs

Proving our commitment to our customer needs, we relaunched our global network of customer collaboration centers as M Lab™ Collaboration Centers. The centers provide customers with a shared, exploratory environment with scientists and engineers working to solve the toughest biomanufacturing challenges. The dynamic setting promotes customer collaboration and problem solving, from pre-clinical through full-scale production. Our scientists and engineers work closely with customers to understand biomanufacturing needs that are then realized within R&D.

In 2016, we committed to provide Provantage® End-to-End development and manufacturing services to Y-mAbs Therapeutics, Inc. in support of Y-mAbs' monoclonal antibody in late-stage clinical development for pediatric brain cancer and also to Acticor Biotech to develop a safe and effective treatment for strokes. Our Provantage® End-to-End solution is a comprehensive suite of products and services that allows biopharmaceutical companies to accelerate the progression of molecules into the clinic and toward commercialization.

Performance Materials

We are the undisputed market and technology leader in liquid crystals (LCs) and photoresist materials, which are primarily used in televisions and mobile communication applications. We are also one of the leading suppliers of OLED materials as well as decorative and functional effect pigments. Materials for integrated circuits round off the portfolio.

Display Materials

We continued to work with our customers, display manufacturers, on the further development of high-performance liquid crystal technologies. These include the multiple award-winning, energy-saving liquid crystal technology UB-FFS (Ultra-Brightness Fringe-Field Switching) for mobile applications. We are additionally testing UB-FFS for non-mobile applications. SA-VA (self-aligned vertical alignment) is the next technology, with which the first products are expected on the market in 2017. It is very eco-friendly and resource-conserving as it requires less energy and solvent in display manufacture. In addition, it is more efficient for display manufacturers because fewer process steps are needed. Since SA-VA technology can be processed at lower temperatures, it is suitable for sensitive materials such as those used in premium products or future applications including flexible displays.

In order to strengthen our position in the increasingly important Chinese market, in September we opened a research and development laboratory for display materials in Shanghai. The new R&D laboratory will focus on the development of new and improved mixtures for liquid crystal displays manufactured in China. This allows us to cover the entire value chain for our customers in China and improve our competitiveness. In addition, we have more strongly positioned liquid crystals under the licrivision™ brand as an innovative material for windows in architectural and automotive applications. We are currently concentrating on three variants: sun protection, glare protection, and privacy control where the windows switch to opaque. Subsequent to the positive resonance to multiple pilot applications for liquid crystal windows, we decided to press ahead with the development and to set up our own production plant for liquid crystal window modules. The development of smart antennas using liquid crystal technology is continuing to make good progress.

Integrated Circuit Materials

In recent years, the cost per transistor for computer chips has not declined to the same extent as in the past. This is a result of the increasingly high cost of photolithography steps, which for modern chips today already amounts to more than 50% of manufacturing costs. This offers us the opportunity to introduce novel, cost-effective materials that allow our customers to counteract this cost development with innovative processes. In spin-on dielectrics, we further strengthened our market position with high-quality, sophisticated materials. Moreover, we successfully launched new products with better performance and better specifications and qualified them in new memory chip production lines. In close contact with our customers, we are also conducting research on new dielectrics that are adapted to the lower process temperature budget of novel chip types. The integration of the former SAFC Hitech business of Sigma-Aldrich has enabled us to combine spin-on technologies with deposition processes and provide customers with both from a single source.

Pigments & Functional Materials

Meoxal® effect pigments based on aluminum platelets are distinguished by their exceptional color saturation and brilliance. We are developing new color spectra for these pigments, which are used especially in automotive and plastic coatings. For Xirallic® NXT, an improved product generation of the well-known high-tech effect pigments, further variants are also under development. The most recently launched pigments include Xirallic® NXT Leonis Gold, a gold-colored pigment with outstanding hiding power and intense glitter, and Xirallic® NXT Tigris Blue, a pure and highly chromatic blue pigment.

In technical applications, we intensified our activities in additives for 3D laser direct structuring with a focus on 3D printing of plastics. We also developed laboratory prototypes together with our partners, which were presented for the first time at the K 2016, the top trade fair for plastics, in Düsseldorf. Laser additives enable computer-controlled fabrication of three-dimensional components with integrated electronic parts and laser-assisted circuit board bonding. We also see potential in energy management. We made good progress in high-voltage technology. Within the scope of the iShield research project, which is funded by the German Federal Ministry of Education and Research (BMBF), we are collaborating with academic and industrial partners to develop novel materials to shield generators and engines. We received the Darmstadt Enterprise Innovation Award for an innovative project with our customer Siemens, in which we are producing additives for more energy-efficient generators. Iriotec® 7340 was the first very light-colored, conductive pigment that we developed to market readiness. It allows a neutral background color that is suitable for every coating color.

We successfully further developed our range of fluorosurfactants, which strongly differentiates itself from competitive products on account of its favorable ecotoxicological profile, among other things. In early 2017, Tivida® FL 3000 is to be added to our portfolio of nonionic surfactants. Even in very low concentrations, it significantly improves the flow and wetting behavior of coating systems.

Besides materials for technical applications, we are also working on innovative raw materials for cosmetics – cosmetic fillers and actives. In cooperation with the French company Agrimer, we launched the first marine active ingredient from a new genetically decoded species of algae. The product known under the brand name RonaCare® RenouMer firms the skin and supports collagen formation.

Advanced Technologies

Organic light-emitting diodes (OLEDs) are an outstanding example of our R&D activities in the Advanced Technologies business unit. We pushed ahead with their further development again in 2016.

In 2016, we realigned our strategic projects for future business fields to megatrends such as miniaturization and the Internet of Things, which are developing at a rapid pace. One of the fields of work that we have derived from these is hybrid electronics. This new generation of electronics can be used, for example, in flexible displays and innovative sensors. Another field is electronic packaging.

Here we see the future in materials that can protect or encapsulate the coming generation of semiconductor elements – also for flexible applications. In both fields of work, we are concentrating on markets in which Merck already holds a leading position, namely display and semiconductor materials. In addition, we are addressing interdisciplinary topics, as smart materials are also gaining importance in the Healthcare and Life Science business sectors. Sensor applications are one such example, which specifically monitor patients' temperature profiles and movements. In the fields of energy storage and thin-film transistors, we are collaborating on projects with partner companies that have introduced new solutions to the market with the help of our innovative products. We also achieved progress in the field of printable organic photovoltaics: In close collaboration with our customers, several mass-producible printing machines were commissioned in 2016. This was made possible thanks to our printing inks, with formulations specifically developed and tailored for customer processes.

People at Merck

Our employees are crucial to our success. Therefore, it is particularly important to us to recruit the right people with the right capabilities at the right time to work for Merck. To support Merck's growth and innovation course, we need a working culture that values diversity, promotes various forms of collaboration and responds flexibly to different requirements. This calls for creative solutions and curious employees who are constantly growing in terms of their professional expectations and skills. This innovative spirit is key to generating new ideas that pave the way to a successful future.

Overview of our headcount figures

As of December 31, 2016, we had 50,414 employees worldwide (2015: 49,613). In 2016, we were represented by a total of 215 legal entities with employees in 66 countries.

DISTRIBUTION OF EMPLOYEES

by region

in %



The future starts now

In a continuously changing world, qualified and creative employees are of tremendous importance. We endeavor to prepare each and every employee not just for today's demands of the workplace, but also for the opportunities and challenges of tomorrow.

A strong starting position

Merck is using the motto "Make great things happen" to position itself in the global job market. The aim is to convey to potential applicants a sense of what makes Merck unique: an inspiring, motivating work environment in which innovations thrive; an environment in which everyone has the opportunity to apply their ideas and engagement to benefit customers and the company, while at the same time developing themselves as employees. To make Merck even more attractive as an employer, in 2015 we repositioned our corporate brand. Consequently, in late 2015, we started an analysis of the impact of the new corporate brand on employer branding. It is essential to harmonize employer branding and messages with the new brand in order to position Merck as an attractive and responsible employer.

When filling open positions, we concentrate on attracting employees who have potential to take on greater roles in the future. For this, we have introduced a globally uniform and binding process. It starts with an internal job posting before external channels such as job portals and recruitment agencies are used. On the one hand, the process offers employees better development opportunities, and on the other hand it minimizes the costs of external recruitment.

In order to support executives in making hiring decisions and to establish uniform quality standards, we offer interview training courses for employees with personnel responsibility. In these courses, the participants learn proper interview behaviors, targeted question techniques and how to incorporate relevant diversity aspects into the hiring decision.

We start integrating new employees before their first day of work, since a good introduction marks the beginning of a successful collaboration. In order to make the onboarding process as efficient and easy as possible for new employees, we have created a welcome website that can be accessed worldwide. Protected by a password, this website is available in eight languages and offers new employees all the information they need. Furthermore, we have set up a special room on our intranet to allow new employees to network and to inform them of important global, local and business-specific issues. In addition, each new employee is assigned an experienced colleague who supports them during their initial orientation period. Our managers are also given a detailed information pack so that they can optimally integrate their new employee into their role. This pack contains an onboarding plan, process descriptions and general information on Merck as an employer.

Success through knowledge

To enhance our growth and innovation potential over the long term and ensure the necessary flexibility to allow us to respond promptly to new trends, we support the development of our more than 50,000 employees. Only by strengthening the abilities of each individual can we count on innovative and curious employees and managers in the future.

This approach starts with good training. In 2016, we again maintained a constant high vocational training rate at Darmstadt, our largest site. A total of 523 motivated young people were enrolled in apprenticeships in 23 different occupations in 2016. We give unlimited employment contracts to all apprentices working in occupations for which we have sustainable demand. On average, the post-apprenticeship hiring rate – taking voluntary terminations into account – was more than 90% over the past five years. Of course we also offer vocational training at other sites in Germany, in which a total of 53 young people participated in 2016.

We continue to promote the professional expertise of our apprentices through numerous regional and global project activities. In 2016, these included supporting a center for homeless children in Ghana.

Furthermore, through our “Start in die Ausbildung” program, we help young people to find an apprenticeship. In 2016, the number of participants was higher than in the previous year, with a total of 22 young people between the ages of 16 and 25. Although they have a school leaving qualification, they had been searching for an apprenticeship for at least one year without success.

In 2016, we established a similar program for refugees for the first time. Through linguistic, technical, cultural, and job-specific training, the “Integrating refugees through training” initiative is preparing twelve young people who were forced to flee their home countries for vocational training and thus for the labor market.

Our advanced training program for all employees comprises a range of globally aligned classroom training courses on 18 selected subjects. In 2016, more than 5,700 employees participated in these courses to prepare themselves for new opportunities and challenges. In addition to classroom training courses, we also offer digital solutions in the form of 200 e-learning and language courses. At workshops designed specifically for teams, employees are taught how to make effective use of individual skills to enhance productivity and collaboration. To enable our employees to realize their full potential, we also provide local business- and function-related offers. All of these measures are documented in globally available development plans.

Moreover, we offer our high-potential staff and senior executives a range of advanced training programs. One of the aims of the six-month International Management program is to promote global thinking among young junior executives and to strengthen their leadership competencies. In cooperation with top international universities, the Merck University has been offering a multi-regional, modular program since 1999. To date, 373 members of top management have taken part. Furthermore, Merck cooperates globally with universities in order to support employees who wish to study for an MBA. In 2015, we launched the Growth Markets

Management program for local executives in India and Latin America, which focuses on business management and Merck-specific topics. This program is also offered in China and Turkey, with participants from a variety of countries and regions such as Africa, the Middle East, Japan, and Russia. Moreover, in 2016 we ran the Managerial Foundation Program in 20 countries with 739 participants and the Advanced Management Program, which was attended by 99 experienced executives in four countries.

Shaping the future through innovation

Innovation plays a particularly important role at Merck. In order to further enhance the preconditions for innovation, in 2015 we opened the modular Innovation Center in Darmstadt. This gives employees the possibility to focus on their ideas and work on projects in an environment that stimulates creativity and collaboration. After all, innovation calls for imaginative employees with adequate scope for creativity and appropriate support, which includes a suitable working environment. Offering our employees various training courses on topics such as innovative methods, creative techniques, and visualizing and testing business models is an important element of the Innovation Center. Internal project teams, start-ups from the Merck Accelerator program as well as many other interested colleagues from various areas throughout Merck benefit from this offer. Recently, the training courses were digitalized, making them available to all employees worldwide.

Driven by inspiration

Furthering the performance culture at Merck to optimally support the company in its transformation and growth program is another focal point of our human resources work. In this context, differentiated compensation and advanced training opportunities are important incentives. Establishing a culture of inclusion and inspiration in which managers set an example through their attitude and behavior, as well as selecting and positioning the right employees, are crucial.

Leading by example

New ideas change the world. That is what drives us. We study things in detail, ask questions and think a step further. This approach is supported by our executives. They recognize and make use of opportunities to drive our innovation-based business model and set their sights on clear goals. At the same time, our executives set an example, for instance by living the Merck values and taking responsibility for their own decisions. In doing so, a differentiated feedback culture is essential in establishing a common vision through effective management. Our competency model supports our executives in further developing our business model and the related culture. The strategic competencies according to which managers and employees are to behave are purposeful, future-oriented, innovative, results-driven, collaborative, and empowering. They enable our executives to build a strong culture of collaboration based on curiosity and trust.

Fostering the skills and potential of our employees

We want our employees around the world to enjoy working at Merck. We want to excite them and retain them. We therefore consider it an important part of our managerial responsibility to identify employee potential early on and foster it on an individual basis. We want to offer our employees interesting career opportunities, continuous personal and professional development as well as prospects within the company. We are thus continuously strengthening our performance and development culture to encourage a curious and innovative attitude among our workforce.

Through intensive analysis of our personnel data using a new software introduced in 2016, we can now more quickly recognize the potential of talented employees, allowing us to fill internal positions even more efficiently. We map our talent and performance management process uniformly for all employees worldwide according to the same principle and via a common IT system. We systematically combine talent recognition with employees' target agreements and performance assessments, since we are convinced that regular feedback helps all employees to grow in terms of their performance and potential. At the same time, regular individual assessments make it easier to identify employees with high potential and to further them accordingly. Clear objectives, differentiated and open feedback and individual development plans are thus important prerequisites for both personal development and business success.

In 2016, we further expanded our workforce pool to internally fill management positions when they become vacant. The vast majority of management position vacancies were filled by internal candidates again in 2016. In addition, we recruited external executives in order to add new perspectives to our long-standing in-house expertise.

Valuing performance

We value the individual contribution of each and every employee and reward them with an appropriate and competitive total compensation. For years, we have been doing this using global processes and programs that are supported by digital platforms. We also offer our executives flexible, market- and needs-oriented compensation instruments. These instruments help to make well-informed decisions and thus continue to provide comprehensible, performance- and position-based compensation.

We aim to be an attractive employer. For this reason we do not only focus on monetary compensation components. Attractive fringe and social benefits also play an important part in motivating and retaining our employees. We have based our "benefits4me" offer on three pillars, namely company benefits including the company pension, health and well-being, and services. There are different benefit packages to meet the various needs of our workforce. Established steering mechanisms ensure that this is a well-made investment in our employees.

Culture makes all the difference

An open, dynamic and inclusive corporate culture and a diverse workforce contribute significantly to our business success. Therefore, promoting diversity and inclusion as well as motivating employees to embrace cultural change are special focal areas of our human resources work.

Unity in diversity

Together with a culture of inclusion, diversity promotes innovation and improves team and individual performance. One of the strategic goals is to recognize the strengths of such a diverse workforce and to appreciate individual differences. It is important to us to create an inclusive work environment in which all employees have the possibility to realize their full potential. With respect to three of our six values, namely respect, transparency and integrity, multifaceted ideas are furthered and perspectives strengthened in order to drive innovation and to add more value. By signing the Equal Opportunity Charter of the German Mining, Chemical and Energy Industrial Union (IG BCE) in 2015 and the "Charta der Vielfalt" in 2013, we underscored our commitment to fairness and tolerance at the workplace.

In addition to the Chief Diversity Officer, who is responsible for strategically managing diversity within the company, Merck also established the Diversity Council in 2013, comprising high-ranking executives from all business sectors and select Group functions. Its aim is to build further active support for and progress in diversity and inclusion within the company. In 2016, the Diversity Council worked to operationalize our Diversity Framework, introduced in 2015, which bundles the diversity and inclusion strategies. It focuses on the following four topics: recruiting the right people to work for Merck, developing and retaining them, promoting efficient collaboration, driving innovations and improvements, and serving customers with diverse needs. In addition, we support specific employee networks in order to foster exchange among like-minded individuals.

In September 2016, we celebrated the Global Diversity Days with a campaign entitled "The Power of Diversity", which aligned with "The Power of We", one of our strategic corporate messages. The objective of this annual month of focus is to heighten awareness of diversity and inclusion among our workforce in global events. Globally, employees in 17 countries across six continents took part in events and shared experiences via employee platforms and social media.

People from a total of 129 different nations work for Merck. Only 23.1% of our employees are German citizens, and 75.3% work outside Germany. Women currently make up 42.8% of the workforce. Since the ratio of women to men varies widely across the different regions, businesses and functions, we have set ourselves the goal of increasing the percentage of female employees wherever they are underrepresented. Here we take into account the situation that is typical for the industry as well as regional differences.

In Germany as well as several other EU countries, Japan and the United States, we are preparing ourselves for demographic change. Since the average age of our employees is slightly more than 40, the need for urgent action does not yet exist; however, we assume that this figure will continue to rise in the coming years. Our focus lies mainly on “mindfulness” as a further step to sensitize the workforce to the limits of their own physical and mental resources.

Among executives, too, inclusion and diversity play a major role. We are convinced that balanced diversity among management enhances career advancement opportunities for talented employees while also helping to provide a broad experience base within the company. In addition, it allows for differentiated decision-making, thereby making a significant contribution to the success of the company.

As a global company, we consider it highly important to have an international management team. Currently, 64.7% of our managers have a nationality other than German. Altogether, 70 different nationalities are represented in such positions. In 2011 we set our strategic goal to increase the percentage of women in management positions to 25% to 30%, which we reached in 2016. The percentage is currently 28.8% at Group level. The figures are steadily increasing across Merck as a whole, but not consistently across business units and Group functions. We have set ourselves the goal for 2021 to stabilize the overall proportion of women in management positions at 30%, but continue to work on increasing the proportion in senior management positions and business units where women are still underrepresented.

The report on stipulations to promote the proportion of women in management positions at Merck KGaA pursuant to section 76 (4) and section 111 (5) of the German Stock Corporation Act, including information on the achievement of the defined targets as of December 31, 2016, can be found in the Corporate Governance section of this report.

Safety in daily work

As a responsible employer, it is especially important to us to do everything in our power to prevent workplace-related illnesses and accidents. We apply the lost time injury rate (LTIR) as an indicator to determine the success of measures aimed at accident prevention as well as occupational health and safety. This key performance indicator describes the number of workplace accidents resulting in lost time of one day or more per one million working hours. In 2010, we had set ourselves the goal of reducing the lost time injury rate to 2.5 by 2015 – with 1.5, we considerably exceeded this target value in 2015. But this still is not enough for us. We believe that nothing is worth an accident. And we have been even more ambitious in setting our goal for the future: By 2020 we intend to sustainably lower the LTIR further. In 2016 we already reached this with 1.3.

The continuous rate of improvement in recent years can be attributed in particular to the BeSafe! program, which was launched in 2010. This is a global initiative with globally harmonized standards, but also local modules that help to meet the specific safety requirements at individual sites. The program focuses on engaging managers in the safety culture and building their buy-in; it aims to make safety an intrinsic value and empower our employees to take responsibility for their own safety. In 2016, we continued to sensitize our employees to workplace hazards through numerous awareness campaigns.

Since 2010, Merck has been presenting the Safety Excellence Award annually in order to underscore the importance of safety. It is granted to all production sites with no workplace accidents on record for the year; in 2016, it was awarded to 61 out of 91 sites.

Flexibility in every situation

As an attractive partner and employer, we endeavor to always provide future-oriented solutions. This also applies to the way in which we work. We want our employees to achieve a good balance between their professional and personal objectives and challenges. This maintains and strengthens their motivation and performance potential for longer, enabling them to better schedule their lives to suit their own needs.

That is why we offer our employees in Germany and the United States various flexible and innovative working models. The “mywork@merck” working model, initially implemented in 2013 at the Darmstadt and Gernsheim sites in Germany for all exempt employees, aims to strengthen a culture of performance and trust within the company. In agreement with their teams and supervisors, employees can choose their working hours and location freely. Since October 2014, non-exempt employees at these sites whose positions are suitable for this working model have also been able to make use of it. In addition, we also introduced “mywork@merck” for Merck Accounting Solutions & Services Europe GmbH, Merck Export GmbH, Merck Schuchardt OHG, Merck Versicherungsvermittlung GmbH, Merck Selbstmedikation GmbH, and Merck Chemicals GmbH. Employees can best decide for themselves, together with their respective line managers, when and how often fixed physical presence in the office is necessary for all team members. Working hours are no longer recorded or monitored. Employees must only document their hours if they exceed their standard working hours within the agreed working time framework. At the end of December 2016, a total of 4,507 employees made use of this model. In 2016, 4.7% of our employees worldwide worked part-time, 10.6% of whom are men. We believe that with these flexible working models, we are on the right track – not only to more efficient processes, but also above all to higher levels of work satisfaction and employer appeal.

We also offer our employees throughout Germany targeted and independent information, advice and assistance in finding childcare and nursing care, as well as home and garden services. At various sites, employees benefit from childcare options that we subsidize. A daycare center, which meanwhile has capacity for 150 children between the ages of one and twelve, has been operating at the Darmstadt site for 49 years. Since 2013, we have been offering expanded, year-round opening hours from 6:30 a.m. to 7 p.m., as well as needs-oriented daycare hour options of 25, 35 or 50 hours per week and, in the adjacent new building, a nursery for up to 60 children between the ages of one and three years. During the orientation phase, our employees can make use of additional offices for parents at the daycare center premises. In addition, a good ratio of staff to children is important to us to offer parents a safe period of supervision for their children while at the daycare center.

Ready for the future

A dedicated, satisfied workforce is key to succeeding as a global company. Only those who question structures and collaborate with others will develop positively. Honest and continuous feedback from our employees is thus absolutely essential so that we are aware of the factors that influence engagement and what the organization's strengths and weaknesses are.

Between December 2013 and June 2015, we conducted the Organizational Health Index (OHI) survey in all business units and Group functions. Based on the results, strategic focus topics were identified and initiatives derived. In 2016 we continued to anchor these topics deeper into the organization.

In order to reach all employees, a global employee survey was conducted in 23 languages in November 2016. Approximately 42,500 employees (83%) took part. Our company-wide score, which measures how engaged our employees are, is 60%. This score is comparable to other companies in the chemical and pharmaceutical industries. As of early 2017, we will be working with the results across the company.

OVERVIEW OF EMPLOYEE FIGURES

		Overall Merck Dec. 31, 2014	Overall Merck Dec. 31, 2015	Overall Merck Dec. 31, 2016 ²
Number of employees	global, total	39,639	49,613 ²	50,414
	by region			
	Asia-Pacific (APAC)	9,488	11,096 ²	10,754
	Europe	20,537	23,429 ²	24,438
	Latin America	3,883	4,352 ²	4,140
	Middle East and Africa (MEA)	639	942 ²	1,045
	North America	5,092	9,794 ²	10,037
Number of employees (FTE – full-time equivalents)	global, total	39,012.4	48,911.1 ²	49,652.7
	by region			
	Asia-Pacific (APAC)	9,474.4	11,068.2 ²	10,725.3
	Europe	19,946.2	22,785.7 ²	23,727.1
	Latin America	3,877.6	4,344.2 ²	4,136.5
	Middle East and Africa (MEA)	637.9	940.6 ²	1,041.8
	North America	5,076.3	9,772.4 ²	10,022.0
Number of countries		66	66 ²	66
Number of legal entities	global, total	146	211 ²	215
Number of employee nationalities	global, total	122	122 ¹	129
Number of nationalities working in Germany		73	77 ¹	91
Percentage of employees with German citizenship		26.6%	26.1% ¹	23.1%
Percentage of employees working outside Germany		71.8%	75.9% ²	75.3%
Percentage of employees with a global manager		5.2%	8.1% ²	9.7%
Percentage of women in the workforce	global, total	41.3%	41.6% ²	42.8%
	in Germany	37.5%	38.2% ²	38.6%
Percentage of women in upper management positions (Global Grade 14 or higher)	global, total	26.3%	26.8% ¹	28.8% ⁶
	in Germany	26.1%	27.3% ¹	28.7% ⁶
Percentage of executives (Global Grade 14 or higher)	global, total	5.5%	5.9% ¹	5.7% ⁶
	Percentage of executives who are not German citizens	60.3%	61.0% ¹	64.7% ⁶
	Number of nationalities	67	64 ¹	70 ⁶
Number of apprentices in Germany		498 ³	506 ⁴	576 ⁵
Vocational training rate		5.4% ³	5.3% ⁴	5.1% ⁵
Percentage of employees in the “mywork@merck” model (Germany)		3,522	4,122	4,507
Percentage of employees working part-time	global, total	5.2%	4.7% ²	4.7%
	men	10.5%	11.3% ²	10.6%
Percentage of employees aged 17 – 29 years	global, total	14.9%	15.2% ²	14.7%
Percentage of employees aged 30 – 49 years	global, total	64.2%	62.6% ²	62.5%
Percentage of employees aged 50 + years	global, total	20.9%	22.2% ²	22.8%
Average age globally		41	41.1 ²	41.3
	by region			
	Asia-Pacific (APAC)	36.6	36.7 ²	36.7
	Europe	42.5	42.4 ²	42.4
	Latin America	39.6	39.5 ²	39.9
	Middle East and Africa (MEA)	37.7	39.5 ²	39.3
Average age by region	North America	44.9	44.2 ²	44.3
	Germany	43.2	43 ²	42.9
Average length of service	global, total	10.1	10.0 ²	9.9
Average length of service in Germany		14.9	14.4 ²	14.2

¹ Excluding Sigma-Aldrich.² Including Sigma-Aldrich.³ Merck KGaA sites Darmstadt and Gernsheim (around 24% of the workforce of the entire Group in 2014).⁴ Relates only to Merck KGaA (around 19% of the workforce of the entire Group in 2015).⁵ All Merck sites in Germany (around 25% of the workforce of the entire Group in 2016).⁶ Not including Sigma-Aldrich legal entities in Germany or Allergopharma.