Global Health & Corporate Responsibility

We are making good progress on integrating ethics, access to medicine, global health and corporate responsibility into the core of our business strategy. In 2019, we pursued changes to strengthen governance; took steps to improve decision-making and reinforce our speak-up culture; further integrated access into how we research, develop and deliver our medicines; and made progress on our environmental sustainability strategy and third-party risk management efforts.

Holding ourselves to the highest ethical standards

As we reimagine medicine, we need to help ensure that our leaders and employees act appropriately when faced with ethical dilemmas and effectively meet society’s increasingly high expectations.

To further reinforce principles-based thinking and ethical decision-making in our organization, we embarked on a journey to move away from our traditional Code of Conduct and develop a Novartis Code of Ethics, a set of values-based principles to guide conversations and decision-making. Building on our Professional Practices Policy, and rooted in behavioral science, the code is being co-created by Novartis people, for Novartis people. More than 2,500 associates shared ideas and insights during early-stage crowdsourcing, and 1,500 participated in a global engagement event to encourage open conversations around ethical dilemmas at Novartis. Development of the code is now underway, with more than 500 associates volunteering to be part of the network that will launch the code in 2020.

We also transformed our whistleblower hotline, the SpeakUp Office, to help ensure we assess and resolve cases promptly, fairly and respectfully. The office is now working even closer with our Global Security organization to drive fair, timely and thorough investigations of higher-risk cases. At the same time, a new process and web-based reporting are driving faster resolution, empowering leaders to respond to day-to-day concerns at the local level.

In addition, we introduced an integrated enterprise risk management (ERM) approach. It is based on risk discussions conducted by the leadership teams of business units at the global level in alignment with their own strategic planning processes, and in close collaboration with all risk functions within units and countries. This process resulted in a single holistic view of risks across the company, known as the Novartis Risk Compass.

We also completed the global rollout of our Third-Party Risk Management program, strengthening our efforts to mitigate risk in our supply chain. In 2020, we aim to expand the program’s scope to include distributors and wholesalers, as well as additional risk areas covering third-party business continuity management and financial risk.

We recognize society’s increasing expectations of our industry and our company. We are constantly learning and remain committed to not only meeting but exceeding these
expectations as we endeavor to increase our positive impact everywhere we work. It is with this mindset that we approached the situation when, in August, the US Food and Drug Administration (FDA) released a statement addressing data integrity issues with the regulatory submission for Zolgensma, our gene therapy for spinal muscular atrophy (SMA). The statement followed the voluntary disclosure by AveXis, a Novartis company, to the FDA, and to other health authorities that some data previously submitted to the agency as part of our submission were inaccurate. The assays in question were used for initial product testing and are not currently used for commercial product release. We immediately initiated an investigation to understand any implications and address the situation. At no time during the investigation did the findings indicate issues with product safety, efficacy or quality. As noted by the FDA, the data in question were a small portion of our overall submission and limited to an older process no longer in use.

We have a firm commitment to data integrity and transparency in our engagements with regulators, and we are confident that the actions we are taking will help prevent data integrity issues from occurring in the future. We swiftly proceeded to implement leadership changes in the AveXis research and development organization, while also taking steps to integrate the AveXis quality organization more formally in the Novartis quality organization. Going forward, and taking the important learnings from this experience, we have voluntarily committed to notify the FDA within five business days of receipt by our quality organization of any credible allegation related to data integrity issues impacting any pending application in the Novartis Group. We will take a similar approach with other regulatory bodies in the absence of specific local regulations.

**Being part of the solution on pricing and access**

We have a responsibility to society to help ensure our innovative treatments benefit more people who need them, no matter where they are. We are making progress with our efforts to systematically integrate access strategies into how we research, develop and deliver our new medicines globally, and we aim to be transparent in sharing successes, challenges and learnings. Expanding access to our medicines is an important measure of our success and is one of the ways we aim to create long-term value for healthcare systems, society and our company.

In 2019, we developed access strategies for all medicines preparing for launch, including Mayzent for multiple sclerosis, Beovu for neovascular (wet) age-related macular degeneration, and Piqray for advanced breast cancer. We also introduced targets to track our progress in reaching patients in low- and middle-income countries (LMICs). For example, in 2020, we aim to increase the number of patients reached with our innovative medicines in LMICs by 20% versus 2019.

**Pursuing R&D for unmet needs**

We are working to incorporate the needs of underserved and neglected populations in our research and development (R&D) programs.

In Latin America, we launched the first-ever multinational clinical study in people with Chagas-
related heart failure, the most important clinical manifestation of the disease, which is responsible for the majority of deaths and disability among patients. The study, which started recruitment in Argentina, aims to assess the efficacy and safety of our heart failure drug, Entresto, in 900 patients. Chagas disease is a potentially life-threatening neglected tropical disease estimated to affect approximately 6 million people, primarily in Latin America. With up to 30% of chronically infected people developing cardiac disorders, Chagas disease is the second leading cause for developing chronic heart failure in the region.

In Africa, we announced that two sites in Ghana and two in Kenya will participate in clinical trials for SEG101 (crizanlizumab), a monoclonal antibody recently approved by the FDA as Adakveo to help prevent the painful and potentially life-threatening complications of sickle cell disease. Recruitment is expected to start in 2020, marking one of the first times that a biologic therapy that is not a vaccine enters multicenter clinical trials in sub-Saharan Africa. At the same time, we are developing a child-friendly formulation of hydroxyurea, the current standard of care for the treatment of sickle cell disease. These efforts are part of our program to improve access to treatment and care for people with sickle cell disease in Africa. Approximately 80% of individuals with sickle cell disease globally are born in sub-Saharan Africa, while more than half of children with the disease die before the age of 5 due to preventable complications.

In September, we announced the European approval of Lucentis for preterm infants with retinopathy of prematurity, making it the first and only licensed pharmacological treatment for this indication. Lucentis is already available as a local brand in many developing countries, and we are committed to working with our teams to further improve access.

We also entered a five-year collaboration with GlaxoSmithKline to fund research into genetic diversity in Africa and its potential effect on therapeutics. The aim is to collect data from currently under-represented regions, with an initial focus on evaluating the potential implications of genetic diversity on the dosing and efficacy of drugs for malaria and tuberculosis.

Driving affordability for lower-income segments

We continue further integrating access strategies into our new product launches. For example, the access strategy for Beovu, co-created across country teams and with input from patients, physicians and payers around the world, includes a local brand strategy as well as plans for novel distribution models and digital solutions to improve diagnosis. We are also developing approaches for one-time gene therapies such as Zolgensma, working with payers to create five-year outcome-based agreements and novel pay-over-time options.

In December, we announced a global Managed Access Program to provide Zolgensma free of charge to eligible patients with SMA who are under the age of two and are a citizen or legal resident of a country where the therapy is not yet approved by regulatory authorities. Recognizing that the program will not be a solution for all families in all countries, we are working to increase supply and design sustainable solutions to further expand access.

Our portfolio of local brands, which takes local affordability into account, is expanding with over 90 brands launched for some of our most innovative medicines across more than 50
developing markets, reaching more than 300,000 patients. For example, currently about 1 in 5 patients on our heart failure treatment, *Entresto*, are receiving a local brand. Through our local brand strategy, we are now introducing some innovative therapies in developing countries within approximately five months of approval in the US or Europe, a process that could have taken several years in the past.

In November, we announced a new strategy to reach more patients in sub-Saharan Africa (SSA) with our portfolio of medicines. As part of this strategy, the regional organization will prioritize driving access to medicines and helping reach more patients across income levels, in addition to traditional business metrics, such as profits and margins. In addition, we plan to continue working with governments and nongovernmental organizations to build stronger healthcare systems. SSA is home to the largest underserved patient population in the world, with a quarter of the global disease burden but only 3% of the world’s health workers.

We continue our efforts to make medicines accessible to people at the bottom of the income pyramid. Novartis Access, which offers a portfolio of medicines to governments, nongovernmental organizations and other institutional customers for USD 1 per treatment, per month, delivered more than 4.5 million monthly treatments since launch to 12 countries in Africa, Asia and Latin America. Further, we signed agreements for implementation in three additional countries. And we expanded our Healthy Family program to more states in India and Vietnam. Overall, the program, which aims to expand access to community education and affordable healthcare for low-income, rural populations, has delivered health education to more than 50 million people since launch.

Building a sustainable healthcare ecosystem

Improving access to medicine and healthcare is a complex challenge that cannot be solved by any one organization alone. We collaborate with public and private partners with diverse capabilities to deliver sustainable solutions.

Through the Bill & Melinda Gates Foundation CEO Roundtable, we are driving an industry effort to expand the training of frontline health workers in developing countries. We each committed USD 1.5 million over three years to further support the efforts of Last Mile Health and Living Goods. The Audacious Project, an innovative funding body, will match the contribution of the partners to reach a total of USD 18 million.

We also launched a partnership with Zipline, a medical logistics company, to help ensure last-mile delivery of our products using drones. In Ghana, Zipline is supporting our collaboration with the government to improve screening, diagnosis and treatment of sickle cell disease by helping ensure that screening tests and medicines are widely available.
Novartis invests in the training and support of scientists and researchers from developing countries through a number of programs and collaborations. For example, our Next Generation Scientist program has hosted more than 180 interns from 30 developing countries since 2011. In 2019, we launched a career development fellowship with the European and Developing Countries Clinical Trials Partnership to facilitate opportunities for early- and mid-career scientists in SSA. We are co-funding at least five fellowships over three years for research proposals in maternal and child health, and specifically on the interaction between poverty-related and noncommunicable diseases.

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**Tackling global health challenges**

For our four flagship programs to fight leprosy, malaria, sickle cell disease and Chagas disease, we are pursuing an end-to-end strategy ranging from the discovery and development of new treatments, to their availability and distribution, and our broader efforts to reinforce healthcare systems.

At the World Economic Forum, we announced a five-year partnership with the Ghanaian government and the Sickle Cell Foundation of Ghana to improve diagnosis and accelerate treatment for people with sickle cell disease, making Ghana the first African country to commit to offering the global standard of care.

In 2018, Novartis registered hydroxyurea, the current standard of care, for the specific indication of sickle cell disease in Ghana, and has since delivered more than 20,000 treatments to 11 trained treatment centers. Our goal is to build a scalable model for addressing sickle cell disease and replicate it in 10 African countries by 2022.

We have also made progress in our commitment to address Chagas disease. In March, we joined the Global Chagas Disease Coalition, an alliance that aims to increase awareness of Chagas disease, foster synergies in controlling the spread of the disease, and promote access to diagnosis and treatment. In parallel, together with the World Heart Federation and the Inter-American Society of Cardiology, we developed an end-to-end roadmap (to be launched in 2020), exploring the patient journey from diagnosis to treatment, in order to identify areas of improvement.

This year, we celebrated the 10th anniversary of the first dispersible artemisinin-based combination therapy developed by Novartis and Medicines for Malaria Venture to treat malaria in children and infants. Since launch, we have distributed more than 390 million treatments in 50 countries, contributing to a significant reduction in malaria deaths.

At the same time, we continue the development of our drug candidates to support malaria elimination efforts and address the emerging threat of artemisinin resistance. Our Phase II trial assessing the efficacy and safety of KAF156 (ganaplacide) in combination with a new once-daily formulation of lumefantrine in adults and children with uncomplicated Plasmodium falciparum malaria has been temporarily paused due to difficulties with the clinical supplies of KAF156. We anticipate restarting the trial in the first half of 2020. Our Phase II dose escalation study to better understand the safety and efficacy of KAE609 (cipargamin) is on
We presented results of the five-year Leprosy Post-Exposure Prophylaxis initiative, implemented by the Novartis Foundation in eight countries to test the real-world effectiveness of preventative treatment for reducing the risk of leprosy in close contacts of newly diagnosed patients. The results, to be published in 2020, showed through epidemiological modeling that large-scale implementation of this strategy could reduce the number of new leprosy cases globally by 75% by 2030 and 90% by 2040.

**Being a responsible citizen**

We aim to conduct business responsibly, wherever we operate. This includes minimizing our environmental impact, helping ensure patient health and safety, and managing risk in our supply chain. In 2019, we established an internal Trust & Reputation Committee, chaired by our CEO, to oversee progress and speed up decision-making in key areas related to the fifth pillar of our corporate strategy: building trust with society. We introduced new management targets covering environmental, social and governance (ESG) topics such as the environment, access to medicines, global health, human rights and third-party risk.

We are investing in renewable energy, such as our wind farm developed with Invenergy, which went online in Texas in the US in 2019. The carbon-free energy it produces entirely covers the electricity currently used at Novartis offices and R&D facilities in the US. We are exploring similar opportunities in Europe.

In addition, we launched a program to phase out single-use plastics at all Novartis sites by 2021, starting with plastic bottles. The majority of our sites around the world have already replaced plastic straws and stirrers, cups, garbage bags and styrofoam with biodegradable alternatives.
The health and safety of the patients our medicines treat is an utmost priority. We are actively combating falsified and counterfeit medicines, which pose a significant threat to public health, and are scaling up efforts to address their root causes. Through our actions, we estimate that we’ve prevented falsified and counterfeit medicines from reaching and harming more than 1.2 million patients since 2017. In 2019, we launched a mobile solution to empower low- and middle-income countries to detect falsified medicines. We deployed 50 smart sensor devices, primarily in Africa, to test medicines in the Novartis Access portfolio, as well as treatments for malaria, heart failure and sickle cell disease. In 2020, we aim to deploy another 200 sensors worldwide, covering the most at risk products in our portfolio.

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