

# Novartis in Society 2019 US Report





# Contents

<b>2019 HIGHLIGHTS</b>	<b>3</b>
<b>FOREWORD</b>	<b>4</b>
<b>SCIENCE AND INNOVATION</b>	<b>5</b>
<b>VALUE AND PRICING</b>	<b>8</b>
<b>PATIENT ACCESS</b>	<b>11</b>
<b>RESPONSIBLE BUSINESS PRACTICES</b>	<b>14</b>
<b>CORPORATE RESPONSIBILITY</b>	<b>17</b>
<b>ABOUT NOVARTIS</b>	<b>19</b>



Matteo enjoys a laugh with his parents, Nicole and Derwin Almeida.

## 2019 Highlights

15 000

Full-time equivalent employees in the US, of whom almost 5 500 are employed at our US-based R&D sites

USD 3.9 BN

Invested in R&D in the US, representing 41% of our global R&D spend that totals USD 9.4 billion

6

Major US regulatory approvals received by Novartis in 2019

520 500

Patients received support through our co-pay assistance program in 2019

299 000

Patients received free medication valued at over USD 7.9 billion through the Novartis Patient Assistance Foundation Inc. over the past five years

Cover image: Matteo Almeida, 4, was born with spinal muscular atrophy, a rare genetic disease that leads to progressive muscle weakness. If left untreated, infants with the severest form of the illness often don't live to see their second birthday. Matteo received a single treatment of a gene therapy, *Zolgensma*, when he was 27 days old as part of a clinical trial.

# Foreword

At Novartis, our purpose is to reimagine medicine to improve and extend people's lives. We do this by unleashing the power of our associates to deliver transformative innovation, embrace operational excellence, go big on data and digital, and build trust with society. This report highlights our progress in advancing these areas to benefit patients and help strengthen our communities and society.

In the Science and innovation section, we outline some of the myriad ways we are using technologies to find new ways to fight disease. For example, our Artificial Intelligence (AI) Lab, being built in collaboration with Microsoft, is expected to help us leverage data and AI to potentially transform how medicines are discovered, developed and commercialized.

Scientific and technological advances are driving a wave of innovations that are opening promising new treatment possibilities for patients, particularly in the emerging area of cell and gene therapies. Novartis is a pioneer in this field, and our breakthrough treatments *Kymriah* for cancer and *Zolgensma* for spinal muscular atrophy already are helping many patients with these life-threatening diseases.

Healthcare systems are accustomed to treating chronic diseases with a pay-as-you-go model, spreading costs over months and years. These systems are currently unprepared to pay for a surge of new, single-treatment therapies with the potential to provide a lifetime of benefit. We understand these novel treatments can be quite costly, and in the Value and pricing section we discuss some of our approaches to price them appropriately. In certain cases we are developing innovative payment models that are based on the value these novel medications deliver to pa-

tients, their families, and our healthcare system.

Patient access has long been a priority for Novartis. In the Patient access section of the report, we discuss some of the many ways we strive to ensure that people get the medicines they need. The Novartis Patient Assistance Foundation remains an essential resource for thousands of patients with no or limited prescription drug coverage. And our Sandoz Division continues to provide high-quality generics as well as biosimilars.

Disparities in healthcare negatively impact many people, families and communities. In the Corporate responsibility section, we discuss the focus of the Novartis US Foundation on addressing the needs of the most vulnerable. In coordination with local groups in communities where we live and work, the Novartis US Foundation seeks to develop innovative and sustainable solutions to expand access to care, build trust in the healthcare system, and support local efforts to address social determinants of health.

As we work to fulfill our purpose of reimagining medicine, we are cultivating a new and clearly defined company-wide culture across Novartis. We want our associates to be inspired by our purpose and curious about ways we can better help patients, physicians, customers and healthcare systems. We also want our people to be unbossed and empowered every day to be their best selves, to achieve their personal and professional goals, and to live our values and behaviors at Novartis.

Integrity is one of our six core values and we continue to place strong emphasis on ethics and compliance. In the Responsible business practices section, we discuss some of the important



Thomas Kendris

steps we are taking to reinforce our commitment to high standards, including by strengthening our Code of Ethics. Our core values also include innovation, quality, collaboration, performance and courage. Together with integrity, these values underpin our company culture and describe the professional behaviors we expect from our associates.

I hope you will take time to read through this report and gain a deeper understanding of some of the many ways Novartis is working hard to build trust with society and deliver more for patients, families and communities. As always, we welcome your comments and suggestions.

Sincerely,  
**Thomas Kendris**  
 US Country President

**WE WELCOME YOUR FEEDBACK:**

→ [uscorporatecommunications@Novartis.com](mailto:uscorporatecommunications@Novartis.com)

# Science and innovation

Nearly 15 000 US-based scientists, physicians and business professionals at Novartis are designing and developing new treatments with the potential to have a significant impact on lives. Together with colleagues across the globe, they are contributing to our industry-leading pipeline of therapies for serious diseases affecting millions of people.

Our consistent investment in research and development – USD 9.4 billion in 2019 alone, including 3.9 billion in the US – fuels our progress. It's also a key pillar of our strategy to build a leading, focused medicines company powered by advanced therapy platforms and data science.

We have the resources and the breadth and depth of expertise to place big bets. We're pursuing drug targets that seem intractable and working on difficult-to-treat diseases. Ninety percent of our treatments in development are anticipated to be first in class or first in a specific medical indication.

Novartis researchers employ emerging technologies to make progress. We're particularly interested in technologies that can be applied to multiple therapeutic areas. For example, we're exploring novel anti-inflammatory compounds that block a cellular danger sensor because they have many potential applications. We recently acquired IFM Tre, a Massachusetts-based company that is developing some of these compounds.

The latest data and digital technologies greatly aid our drug development process. Our R&D teams are harnessing advances in machine learning and predictive analytics to transform the way we work. This includes mining petabytes of data – from images of cells to patient

test results from thousands of clinical trials – for insights.

## Advanced therapy platforms

We're exploring new ingredients for medicines such as genes and therapeutic viruses, fundamentally rethinking the tools in a drug hunter's arsenal. This work centers around advanced therapy platforms—broadly applicable tools with the potential to become therapeutic staples and game-changers for patients.

A good example of this approach is adeno-associated viruses (AAVs) – small, benign viruses that can be used to deliver genes to cells inside the body. AAVs are already powering a wave of innovative gene therapies, including our new treatment *Zolgensma*.

This novel medicine was approved in 2019 in the US for spinal muscular atrophy (SMA) in patients less than 2 years old who have mutations in both copies of a gene called survival motor neuron 1 (SMN1). Infants with the most severe form of the disease, SMA type 1, rapidly lose the motor neurons responsible for muscle functions such as breathing, swallowing and walking.

Scientists at AveXis, a Novartis company, designed *Zolgensma* to address the genetic root cause of the disease in

an attempt to halt disease progression. Teams are developing additional AAV-based gene therapies for conditions of the central nervous system and the eye.

We continue to build on the success of our flagship CAR-T therapy, *Kymriah*. Chimeric antigen receptor T-cell (CAR-T) therapies involve extracting and reprogramming a patient's T-cells to recognize and fight cancer cells before being infused back into the patient, where they become a "living drug." *Kymriah* is approved in the US and other countries for certain pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. It's also approved in these countries for a particular type of relapsed or refractory large B-cell lymphoma in adult patients.

Some of the first recipients of *Kymriah* have shown no signs of relapse for more than five years, but not all patients have such a positive outcome. We're designing new CAR-T therapies and exploring how to combine them to overcome resistance and relapse in a variety of difficult-to-treat cancers, including other hematological cancers and solid tumors.

Our pioneering work with novel technology extends to other areas as well. For example, researchers at Advanced



Matteo's mother teaches him to write.

Accelerator Applications (AAA) and Endocyte, both Novartis companies, are developing radioligand therapies, targeted drugs that are designed to deliver radiation to tumors.

Novartis scientists are also creating a new class of therapeutics called synthetic glues to short-circuit disease cells and treat serious illnesses. Four of our experimental glues have already entered clinical testing for the treatment of certain cancers and immunologic and neurodegenerative diseases.

### **Data science and digital technologies**

Novartis is a data powerhouse. We've collected approximately 2 million patient-years of data through our clinical trials alone. And we're taking steps to make the most of this strategic asset, applying emerging tools to scale so we can bring treatments to patients faster while reducing costs.

Data42 is a program that's laying the technical and cultural foundation for a revolution inside our organization. We're integrating massive amounts of data that previously existed in silos and using machine learning and artificial intelligence to mine it for important connections and patterns. Novartis data scientists are building models and applications that will empower teams to prioritize drug targets, identify development opportunities for compounds, and more.

Similarly, our collaboration with the University of Oxford's Big Data Institute will draw on data from multiple sources. The team will develop new machine learning algorithms and identify patterns across massive datasets. The goal is to better understand disease and predict how patients will respond to existing and new medicines.

We're systematically employing data and digital tools to benefit patients in myriad ways. To improve patient participation

in research, for example, we're using a platform developed by Verily, an Alphabet company, to test digital recruitment for clinical trials. And we're working with Pear Therapeutics to design and test a prescription digital therapeutic for treating depressive symptoms in patients with multiple sclerosis, a project with potential applications in other diseases.

### **Advancing transformative therapies**

We explore areas that are difficult for other companies to pursue, yet where there is high unmet need for patients. We have the scale as well as the breadth and depth of scientific expertise to venture into new frontiers, take smart risks, and attack problems from multiple angles.

Our big bets include CFZ533, an experimental immunomodulatory therapy with the potential to make kidney and liver transplants more durable, and TQJ230, a novel molecule designed to

alter messenger RNA (mRNA). TQJ230, an investigational therapy which we recently in-licensed, has the potential to be the first medicine approved to treat patients with elevated levels of lipoprotein(a) and established cardiovascular disease.

As we pursue these and other innovative projects and evolve our approach to research and development, we remain focused on delivering new treatments for patients. In 2019, we launched several medicines in addition to *Zolgensma*, our novel gene therapy. These treatments have the potential to change the standard of care for devastating diseases. We also shared promising clinical trial results throughout the year.

### **Ophthalmology**

We received approval in the US for *Beovu*, a biologic drug designed to treat neovascular (wet) age-related macular degeneration (wet AMD), in October 2019.

### **Neuroscience**

In March 2019, we launched *Mayzent*, the first oral drug approved to treat active secondary progressive multiple sclerosis, an advanced form of the autoimmune disease. The US Food and Drug Administration (FDA) approved our therapy based on trial results that showed it significantly reduced the risk of disease progression, including impact on physical disability and cognitive processing speed.

We continue to search for new solutions for multiple sclerosis and reported strong Phase II results for ofatumumab in patients with relapsing forms of the disease. If approved, ofatumumab will potentially become a treatment for a broad relapsing multiple sclerosis population and the first B-cell therapy that is easy to manage in a monthly self-administered injection at home.

### **Oncology and Hematology**

This year we received approval in the US and other markets for *Piqray*. It is a targeted, small molecule drug designed to inhibit the effects of a mutation in the gene PIK3CA, the most commonly mutated gene in HR+/HER2- metastatic breast cancer, for postmenopausal women, and men, whose disease has progressed on or after endocrine (hormone) therapy.

In hematology, we advanced a treatment for sickle cell disease, a debilitating inherited genetic blood disorder. In November 2019 we received approval for *Adakveo* in the US for reduction of sickle cell pain crises, which are unpredictable, severe events associated with life-threatening complications. The approval was based on data showing reduction in the annual rate of vaso-occlusive crises in patients with sickle cell disease.

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In 2019 we continued to sharpen our company's focus on innovative medicines. We completed the spin-off of our Alcon eye care division while maintaining our strong position in ophthalmic pharmaceuticals, including acquiring Xiidra, which is approved to treat signs and symptoms of dry eye. We also made progress against our portfolio strategy in our Sandoz Division, including the pending sale of a portfolio of approximately 300 medicines and dermatology products and product families in the US to Aurobindo.

In early 2020, we acquired The Medicines Company, which has developed an investigational cholesterol-lowering therapy called inclisiran. This small interfering RNA molecule reimagines the treatment of atherosclerotic heart disease and familial hypercholesterolemia. The Medicines Company submitted a New Drug Application for inclisiran with the FDA in late 2019.

# Value and pricing

At Novartis, we are pushing the boundaries of science to reimagine medicine and bring the benefits of transformative innovation to patients everywhere. As part of this commitment, we are working diligently with a wide range of stakeholders to ensure that patients have access to the latest therapies; that these therapies are properly valued and rewarded by the healthcare system; and that we place higher value on the impact medicines have on human health rather than the volume of treatments the healthcare system delivers.

## Making the US healthcare system better for all

With important new medical breakthroughs in the clinic and on the horizon – including cell and gene therapies, which offer new hope for patients with deadly diseases – Novartis believes it is imperative for us to act now. We must accelerate a fundamental transformation in the US healthcare system to support access to novel therapies while also rewarding innovation and risk-taking.

We recognize the extent and complexity of this challenge and are committed to working constructively with all stakeholders, including policymakers, healthcare providers, patients and many others. Our goal is to find solutions that will support sustainability and reduce waste, while not compromising our ability to drive development of the next generation of innovative medicines, generics, and biosimilars.

## What Novartis is doing now

We are taking significant steps to accelerate the evolving role of medicines in our healthcare system. For example, we are focusing much of our research and development work on treatments that have the potential to significantly change the standard of care for patients, including potentially curative, one-time cell and gene therapies.

One of these exciting therapies is *Zolgensma*, a treatment approved in May 2019 to address the root cause of spinal muscular atrophy (SMA), a genetic disease that, when left untreated in its most severe form, may lead to permanent ventilation or death for most patients by age two. *Zolgensma* works by replacing the defective or missing SMN1 gene to halt disease progression with a single one-time infusion.

Submission of Investigational New Drug applications to the FDA are expected in 2020 for potential treatments for Rett syndrome and a genetic form of ALS, also known as Lou Gehrig's disease.

To address the cost associated with these new therapies, Novartis has introduced novel measures that tie payment to outcomes. And we are laying the groundwork for more ambitious risk-sharing approaches for future innovative products. In the case of *Zolgensma*, we are working closely with payers to offer payment-over-time options for up to five years through a third party, and outcome-based agreements with terms up to five years. As of the end of 2019, we have outcome-based agreements in principle for *Zolgensma* with nearly all private and commercial payers.

In addition to outcome-based or value-based agreements for *Zolgensma*,

we have innovative agreements in place for *Cosentyx* and *Entresto*, as well as for *Kymriah*, our transformational personalized treatment for certain deadly blood cancers. We are moving toward value-based agreements for other therapeutic areas as well.

Novartis has been a leading voice in recommending the industry shift to a value-based pricing and contracting approach, with reasonable out-of-pocket costs for patients, as one of several solutions to delivering sustainable healthcare. We are also encouraging greater use of generics as an effective way to hold down drug spending. Ninety percent of prescription drugs in the US are generics and the US healthcare system has saved over USD 2 trillion over the last ten years through their use. We estimate that our medicines helped save the US healthcare system around USD 12 billion in 2018 and USD 101 billion in the last decade.

We also advocate for the faster development of and easier access to biosimilars – copies of large molecule biologic drugs – by removing impediments to their creation and use. We believe that significant progress can be made with science-based regulatory measures that are relatively easy to implement and provide the proper incentives to drive greater utilization of biosimilars. Our Sandoz Division – a global leader in



**US product portfolio<sup>1</sup> – % change vs. prior year<sup>2</sup>**

	2015	2016	2017	2018	2019	5 year average
<b>Total gross price change<sup>3</sup></b>	9.3%	6.2%	5.4%	5.6%	4.9%	6.3%
<b>Total net price change<sup>4</sup></b>	1.3%	-2.0%	-2.1%	-1.1%	2.9%	-0.2%

90%

of prescription drugs in the US are generics

<sup>1</sup> US product portfolio for 2015 to 2019 includes all medicines sold by the US Innovative Medicines Division, including Alcon Ophthalmics products as applicable, medicines sold by AAA, AveXis, and the US Sandoz Division.

<sup>2</sup> The company's calculation of gross and net price changes were subjected to agreed upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400. Our methodology may differ from the methodologies used by other companies. This pricing information should not be read in conjunction with the company's filings with the Securities and Exchange Commission.

<sup>3</sup> Represents the year-over-year change in the average list price of Innovative Medicines brands, combined with the year-over-year change in the average wholesale acquisition cost (WAC) of the Sandoz products that had an increase in gross price in the period. Individual gross price changes by brand or product are weighted by current year gross sales.

<sup>4</sup> Represents the year-over-year change in the average net price. The net price is the total gross price less total rebates, discounts and deductions.



biosimilars – has 8 biosimilars approved globally and more than 10 in the pipeline.

### Managing price adjustments responsibly

At Novartis, we aim to price our medicines responsibly, based on the value they deliver to patients, healthcare systems and society. In the US, we implemented guidelines for limiting average net price increases across our portfolio to the healthcare inflation rate, and we publish our average gross and net price increases annually in this report.

In 2019, the average gross price increase across our portfolio was 4.9%. However, our average net prices over the same period were only 2.9%. In the US, our average gross price increase from 2015 to 2019 was 6.3% while our average net price decreased by 0.2%. Gross price (also called list price or wholesale acquisition cost) is the starting price set by the pharmaceutical company. Net price reflects the final amount received by the company. The difference between the gross and the net price is largely the result of many negotiations that take place between the pharmaceu-

tical company and other stakeholders in the supply chain, such as government payers, insurers, pharmacy benefit managers, wholesalers, retailers and hospitals. These negotiations typically result in the pharmaceutical company paying discounts, rebates, and fees to the stakeholders in the supply chain, which decreases the gross price.

These discounts and rebates are not directly passed on to the patient, meaning that net prices often differ from the final costs absorbed by payers and patients. Further, stakeholders in the supply chain may apply additional charges and fees, increasing drug prices above the discounted amount charged by the manufacturer.

In the US, the total annual rebates and discounts on Novartis products (both innovative medicines and Sandoz generics) increased from 45.8% in 2015 to 48.4% in 2019.

Novartis publishes key financial information annually in its Form 20-F and Annual Report, including total rebates, research and development costs, and gross and net sales.

# -48.4%

the total annual rebates and discounts on Novartis products

	2015	2016	2017	2018	2019
<b>Total US rebates and discounts<sup>1,2</sup></b>	-45.8%	-47.7%	-49.5%	-49.8%	-48.4%

#### KEY CORPORATE PUBLICATIONS:

→ [www.Novartis.com/news/publications](http://www.Novartis.com/news/publications)

<sup>1</sup> Total US rebates, discounts and deductions calculated as a percentage of total gross sales.

<sup>2</sup> The company's calculation of the total rebates and discounts % were subjected to agreed upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400.

# Patient access

We believe that medicines should be available to all who need them. The Novartis Access Principles help us keep access at the heart of our business. Patient access is integrated into our product strategies beginning with the initial research and development (R&D) stage, with the goal of ensuring that our treatments reach patients broadly, including people in need. We also are committed to improving the affordability of medicines and strengthening healthcare systems broadly.

## Our Commitment to Patients and Caregivers

Novartis knows that only by working together can we improve outcomes for patients and change the practice of medicine. Our four-part Commitment to Patients and Caregivers makes it clear what they can expect from Novartis.

### 1. Respecting and understanding the patient community perspective

We commit to:

- Actively seek out and listen to the patient perspective in all stages of development and commercialization of our medicines;
- Provide educational opportunities that empower patients to seek the right care and help healthcare professionals best treat their patients;
- Work to make our products easier to use, especially for patients living with physical limitations;
- Provide easy-to-understand information about our products as well as timely and accurate medical information about our products to healthcare professionals;
- Fully respect the patient community's independence and integrity, and to work in a simple, transparent way.

### 2. Expanding access to our medicines

We commit to:

- Work with the patient community and other stakeholders to help get patients the medicine they need;
- Implement access strategies for all our new medicines based on the principles of addressing the needs of underserved populations through R&D, further improving affordability of our medicines, and strengthening healthcare systems;
- Continue providing tailored and scalable access solutions, such as patient assistance programs, new payment and business models and drug donations, and bringing generics and biosimilars to market through our Sandoz Division;
- Explore options to provide patients with access to our investigational medicines, if requested, prior to regulatory approval.

### 3. Conducting responsible clinical trials

We commit to:

- Seek patient input and preferences early in the drug development process and improve how we share information with patients before, during and after a clinical trial;
- Use insights from patients in clinical trial designs, exploring novel

In 2019, Novartis co-pay assistance programs helped nearly 520 500 patients.

#### FIND OUT MORE ABOUT OUR ACCESS PRINCIPLES AT

→ [www.Novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/access-principles](http://www.Novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/access-principles)



technology-enabled solutions and implementing strategies to ensure that our trials reflect the diversity of patients;

- Give the patient community and others access to trial information, including outcomes, whether positive or negative;
- Provide results of completed Novartis clinical trials on [clinicaltrials.gov](https://clinicaltrials.gov) (for the US) and [EudraCT](https://eudract.europa.eu) (for the European Union). We also ask the independent sponsors of all Investigator Initiated Trials supported by Novartis to make all their results public;
- Register our new medicines in every country where patients have participated in trials. Where a medicine is registered but not commercially available, we commit to provide it, as permitted by local law, to patients who participated in trials to ensure their treatment is not interrupted.

#### **4. Recognizing the importance of transparency and reporting**

We commit to:

- Transparently share information about our interactions with healthcare professionals and the patient community, and to disclose all financial and relevant non-financial support;
- Regularly report progress on these commitments.

### **Expanding the impact of the Novartis Patient Assistance Foundation**

The Novartis Patient Assistance Foundation Inc. (NPAF) provides medicines at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage. In 2019, NPAF provided nearly USD 2.7 billion in free medicines to more than 87 000 patients in the US, covering more than 75 medicines from our portfolio. Over the past five years, medication valued at roughly USD 7.9 billion has been made available at no charge to nearly 300 000 patients.

NPAF continues to find ways to improve the patient experience and drive efficiencies. One way is through a streamlined patient-friendly application that reduces processing and fulfillment time. In addition, to connect more quickly with patients, the NPAF launched an automated texting platform, enhancing the refill process and reducing the time to communicate with patients. Implementation of an electronic benefit verification program to screen patient insurance information and aid with insurance reverification is expected in 2020.

NPAF has expanded access to Novartis medicines launched in 2019, including *Beovu* (wet age-related macular degeneration), *Mayzent* (multiple sclerosis) and *Piqray* (breast cancer). In addition, NPAF's Institutional Patient Assistance

Program (IPAP) now includes ophthalmology and cardiovascular products and has increased its partnerships with safety-net clinics, which provide healthcare services to indigent populations in the US. IPAP clinics receive Novartis medications directly and handle patient enrollment and processing. This allows patients to walk in and receive the medicines they need almost immediately, filling a critical gap in the healthcare system.

### **Improving affordability for patients with insurance**

Every year, Novartis helps thousands of patients with commercial insurance access our medicines at reduced cost to them. Through our co-pay assistance programs in the US, eligible patients pay no more than USD 30 for a 30-day prescription (USD 1 per day) for the vast majority of our branded and biosimilar products, including our cancer portfolio. Our co-pay assistance programs are subject to limits imposed by a patient's individual health plan, pharmacy benefits manager, or employer, and where allowed by law. Due to current regulations, co-pay assistance is not available to patients covered by government healthcare programs, such as Medicare and Medicaid.

## Addressing sickle cell disease on multiple fronts

When it comes to fighting serious diseases, patients need access to effective medicines – and much more. In many cases they also need help tapping into resources that can inform, educate and support them and their families. Patients with sickle cell disease (SCD) – a painful and debilitating blood disease affecting approximately 100 000 people in the US – can feel especially isolated and confused about their condition.

Last year, Novartis joined with a number of patient advocacy organizations to launch Generation S, a national sickle cell storytelling project designed to encourage the SCD community to break their silence about the impact and burden of

the disease. Since the program's inception, people within the sickle cell community have shared more than 1 000 stories on the website, JoinGenS.com. Participants say they feel part of a broad community that understands their special needs and concerns about SCD.

Novartis is also supporting non-profits that work with the SCD community as part of our *STEP (Solutions to Empower Patients)* Program, now in its third year. Through this initiative, Novartis provides funding support to US-based nonprofit organizations that deliver innovative solutions to address unmet patient needs or gaps in care. In 2019, our *STEP* Program focus was on SCD, and we provided support to five organizations, committing nearly USD 250 000.

## Patient Support Services

In addition to co-pay assistance, Novartis helps patients navigate the complex US health insurance system to make it easier for them to start and stay on our life-saving medications. Support services are provided for free and include benefit investigations, injection demonstrations, required product initiation testing, and educational adherence programs. Helping patients this way could ultimately impact longer-term health outcomes and reduce overall costs for the US healthcare system.

## Expanding patient access and saving money with off-patent medicines

Generics play a critical role in furthering access to medicines. In the US, our Sandoz Division is focused on biosimilars, generic injectables, and ophthalmic and respiratory medicines. In 2019, Sandoz launched several specialty

generic medicines, including *Symjepi* (epinephrine) Injection for emergency treatment of allergic reactions, including anaphylaxis; *Fulvestrant Injection* for breast cancer; and *Treprostinil Injection* for pulmonary arterial hypertension.

Biosimilars may enable more patients to access advanced biologic medicines earlier, and Sandoz has proven that biosimilars offer significant cost savings for overburdened healthcare systems. In fact, Sandoz saved the US healthcare system nearly USD 500 million in less than two years as a result of the successful adoption of one of our oncology supportive care biosimilars, *Zarxio* (filgrastim-sndz), into clinical practice. We expect to see further savings with a second oncology supportive care Sandoz biosimilar, *Zlextenzo* (pegfilgrastim-bmez), which launched in the US in 2019. Sandoz continues to lead this effort, with eight biosimilars approved globally – including four in the US – and more than ten in the pipeline.

### FIND OUT MORE ABOUT OUR PROGRAMS:

Novartis patient assistance programs  
 → [www.patientassistancenow.com](http://www.patientassistancenow.com)  
 → [www.pap.Novartis.com](http://www.pap.Novartis.com)

Novartis Pharma Universal Co-Pay Program  
 → [www.copay.Novartispharma.com](http://www.copay.Novartispharma.com)

Novartis Oncology Universal Co-Pay Program  
 → [www.copay.Novartisoncology.com](http://www.copay.Novartisoncology.com)

Novartis Oncology Patient Support  
 → [www.patient.Novartisoncology.com](http://www.patient.Novartisoncology.com)

# Responsible business practices

Integrity is one of our core values at Novartis – along with innovation, quality, collaboration, performance and courage. These values underpin our company culture that aims to be inspired, curious and unbossed. Together, our culture and values help us fulfill our purpose of reimagining medicine.

## Ethics and Compliance

Novartis believes that responsible business practices start with holding ourselves to the highest ethical standards. We have a strong compliance system in place to help us monitor and enforce our integrity standards companywide, and we are continuously improving it. This includes investing in training for our associates, with high completion rates in the US for our Code of Conduct (98.7%) and our Culture of Integrity (99.0%) courses.

We have simplified our Professional Practices Policy to help our associates make better decisions and are using data analytics to aid us in predicting risk. To foster greater trust with patients, healthcare practitioners, government officials and the public, we are committed to disclosing all financial and relevant non-financial support in our interactions with healthcare practitioners and the patient community.

We also want to make sure our associates feel safe and empowered to speak up when they see something questionable. Our SpeakUp process is designed to be impartial and confidential, and to treat all associates with respect. It has been updated to ensure that we maintain an efficient, simplified and accessible way for all associates to report and

address any concerns about unethical behavior as quickly and effectively as possible.

In 2019 we initiated a companywide effort to create a new Code of Ethics, which will further reinforce principles-based thinking and ethical decision-making in our organization and in our interactions with external stakeholders. The Code is being co-created by Novartis associates, for associates, using a variety of innovative tools to gather perspectives and facilitate dialogue. More than 4 000 associates have participated in the process so far as we prepare to launch the new Code in 2020.

## EPIC Pledge

Novartis is taking concrete measures to advance pay equity and transparency companywide. In 2018 we were proud to join the United Nations' Equal Pay International Coalition (EPIC). As part of this commitment, Novartis pledged to monitor pay equity with global consistency, remove bias from the system, create pay transparency, and improve gender balance in management.

We made progress in 2019 toward the EPIC pledge to close the gender pay gap by 2023, including by eliminating historical salary data when making job

**MORE INFORMATION ON THE PROFESSIONAL PRACTICES POLICY IS AVAILABLE AT**

→ [www.Novartis.com/our-company/corporate-responsibility/ethics-risk-compliance/professional-practices](http://www.Novartis.com/our-company/corporate-responsibility/ethics-risk-compliance/professional-practices)



offers in the US and other countries. In 2020, we plan to introduce pay transparency in the US and seven additional countries.

## Environmental sustainability

We believe businesses should act responsibly by promoting greater environmental sustainability. We collaborated with Invenergy on the Santa Rita East wind farm in Texas, which went online in 2019. In the first three months of operation, our portion of the wind farm generated more than 93 000 MW of power, which is the equivalent of enough electricity to power over 6 600 average homes in Texas for an entire year.

The climate emissions from all the electricity we use at Novartis offices and R&D facilities in the US are now fully offset, thanks to the renewable energy credits generated by this wind farm through the virtual power purchase agreement.

We are moving forward with our initiative to create a plastics-free workplace at Novartis, including phasing out all single-use plastic materials in our cafeterias and other facilities. In the US we now have completely eliminated use of polystyrene (Styrofoam) in our food services operations. In our Novartis In-

stitutes for BioMedical Research (NIBR) division, we are assessing our plastics use and developing strategies to reuse laboratory consumables and find more environment-friendly substitutes.

## Policy contributions and advocacy

Healthcare continues to be prominent in debates and discussions across the US. For this reason, Novartis is committed to engaging with policy leaders and other external stakeholders as we seek solutions to help patients and strengthen our healthcare system.

## Lobbying

Through lobbying, Novartis is able to pursue constructive dialogue with officials to assist them in making informed decisions on healthcare policy, such as ensuring patient access to innovative therapies. Armed with data, insights, best practices, and ways to improve patient outcomes, the company's public affairs team works to support the most productive regulatory and legislative environment for our business and the patients we serve.

Regarding the use of external lobbying-related resources, we understand more than ever the importance of strengthening the relevant contract-

ing and due diligence processes. For example, before Novartis engages political consultants, we now secure an independent third-party due diligence report.

Federal and state laws dictate what falls under lobbying in terms of expenditures, reporting, and registration, which is further clarified through guidance from the United States Senate and US House of Representatives. The intent of the federal law is to provide transparency and accountability regarding persons who appear before the federal government advocating for policies that would protect or benefit their constituencies. Not all government affairs-related activities are considered lobbying, but many of them are. Included in the amount disclosed are labor hours of all Novartis officials who engage in lobbying, consultants and third-party expenses, and the portion of trade association dues related to lobbying. Registered state lobbyists comply with all reporting requirements as defined by each state.

## Financial political contributions

Novartis engages with political leaders on issues of importance to our industry, such as patient access, intellectual property and digital health. Novartis only makes financial political contributions in countries where such contributions



by corporations are legal and considered consistent with our commitment to transparency, honesty and integrity. In the US, Novartis makes direct political contributions at the federal level and also at the state level, where use of corporate funds is permissible by state law and otherwise considered appropriate.

In 2019, Novartis made political contributions totaling USD 1 112 459 in the US. This figure includes:

- Contributions to state-oriented political groups, as permitted by state law (USD 367 500);<sup>1</sup>
- Contributions to federal political groups that focus on specific policies or issue areas at the national level, as permitted by federal law (USD 25 000);
- Contributions using corporate funds to candidates and political committees at the state level (approximately USD 513 670<sup>2</sup>) in states where this is permitted; and
- Contributions from the Novartis Political Action Committee (PAC) to federal candidates, federal party committees, and some state candidates and caucuses, as permitted by law (USD 206 289).

The Novartis PAC only uses funds received from individual participating employees (but not from the company) to make political contributions. These contributions are reported monthly to the US Federal Election Commission (FEC) and twice a year to the Clerk of the US House of Representatives and the Secretary of the United States Senate.

Reports disclosing the sum of federal lobbying-related activities and PAC contributions are all available for public access and can be found on the respective websites of the FEC, the US House of Representatives' Office of the Clerk and the United States Senate's Office of the Secretary.

#### FIND OUT MORE

- [www.fec.gov/data/](http://www.fec.gov/data/)
- [clerk.house.gov/public\\_disc/index.aspx](http://clerk.house.gov/public_disc/index.aspx)
- [soprweb.senate.gov/index.cfm?event=selectfields](http://soprweb.senate.gov/index.cfm?event=selectfields)

<sup>1</sup> Receipt of funds by these groups is in compliance with applicable laws, regulations and guidelines.

<sup>2</sup> This number represents the total amount of pledged political contributions in 2019, though the actual value of contributions given could be smaller due to the changing nature of campaigns and other administrative issues.

# Corporate responsibility

As a leading global pharmaceutical company, Novartis is committed to finding innovative ways to improve the health and well-being of people everywhere. In support of this, our corporate responsibility efforts in the US aim to increase access to care and advance health equity among the most vulnerable populations in the communities where we live and work.

We accomplish this by collaborating with community-based organizations to address strategic priorities related to healthcare, education and local community needs. We also strive to unleash the power of our people to have social impact, as volunteers in their communities, mentors in schools and organizations, and donors to important charities and causes.

## The Novartis US Foundation

In 2019, the Novartis US Foundation laid the groundwork for more impactful corporate responsibility efforts in the US. Our goal is to expand our efforts around a new mission to improve health in underserved communities throughout New Jersey and across the US. We do this through programs and collaborations that aim to:

- Build trust among patients and providers in disadvantaged communities, including by addressing implicit bias and increasing diversity in the healthcare workforce;
- Remove barriers to care, including by increasing access to enabling services among the most vulnerable populations and strengthening the integration of innovative solutions into healthcare systems; and
- Support local communities, such as funding local community efforts to address social determinants of health and ensuring community preparedness for disaster response throughout the US.

In addition, the Novartis US Foundation continues the company's legacy of supporting local community organizations. In 2019 we provided USD 1.1 million in funds to support local community groups as well as key disaster relief organizations. Many of these local community groups are working to effect change across New Jersey, where Novartis has a strong presence. For example, organizations such as the Community Food Bank of New Jersey are addressing food security and other social issues that have a significant impact on health and quality of life.

On the national level, one of several programs we support is the American Red Cross "Ready 365" program. This initiative provides sustainable support that allows the Red Cross to respond immediately to provide shelter, food and other basic needs following disasters – ranging from house fires to major hurricanes.

## Volunteering to build trust in local communities

Many Novartis US associates are helping to build trust in local communities by

## FIND OUT MORE

→ [www.pharma.us.novartis.com/corporate-responsibility/corporate-citizenship/people-and-communities](http://www.pharma.us.novartis.com/corporate-responsibility/corporate-citizenship/people-and-communities)



actively participating – on their own time – in our corporate responsibility initiatives.

As a company built on scientific innovation, Novartis believes it is important to start early to inspire, motivate and educate students about careers in science, technology, engineering and mathematics (STEM) subjects. Over the last year, we have increased that commitment through several STEM education programs that provide not only financial support, but also opportunities for Novartis associates to participate directly in advancing the goals of these initiatives.

In 2019 we enhanced our more than thirty-year partnership with the Independent College Fund of New Jersey to provide mentorship opportunities to recipients of Novartis Science Scholarships. This scholarship program supports students pursuing independent research at their university.

The new mentoring component connects students with highly respected and accomplished science professionals at Novartis. Students and

mentors interact in person, by phone or over Skype several times in the academic year. This program offers students meaningful experiences that will help guide them in pursuing future careers in science. And it gives our associates a unique opportunity to inspire curiosity and passion in the leaders of tomorrow.

We also have worked with the New Jersey-based nonprofit Students 2 Science (S2S) to deliver an authentic, state-of-the-art laboratory experience to primary and secondary students. To broaden the reach of this initiative to underserved students, Novartis is supporting the S2S Virtual Laboratory (V-Lab) program, a remote web-based solution that eliminates geographic and language constraints.

Novartis associates are key participants in these programs, working side-by-side in the lab at the S2S facility in East Hanover, NJ, as well as participating in V-Lab activities. They also volunteer to build V-Lab experiment kits for use in the sessions.

In Massachusetts, where the Novartis R&D organization is headquartered, associates volunteer in several important science education and community outreach initiatives.

The Community Exploration & Learning Lab (CELL@Novartis) in Cambridge, MA, strives to excite local youth about biomedical science and drug discovery through hands-on experimentation and minds-on problem solving. In 2019, CELL@Novartis hosted approximately 700 students from over 20 schools and programs, engaging 100 Novartis scientist volunteers.

In addition, more than 800 Cambridge-based associates provided more than 3 500 hours of service in volunteer activities in the greater Boston area, including Community Partnership Day and the Cambridge Science Festival.

# About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109 000 people of more than 140 nationalities work at Novartis around the world. Find out more at [www.novartis.com](http://www.novartis.com).

In the US, Novartis has nearly 15 000 full-time equivalent employees in skilled positions across 18 locations. We have five headquarter campuses: East Hanover, New Jersey; Princeton, New Jersey; Cambridge, Massachusetts; Indianapolis, Indiana; and Bannockburn, Illinois.

## Global health and corporate responsibility at Novartis

Novartis has a strong history of global health and corporate responsibility (GH&CR) activities, and transparent reporting is a central part of our commitment. We have reported on CR since 2000 through our Annual Report and several online and printed materials.

The Novartis in Society Report consolidates the company's GH&CR reporting and details our progress against our targets. The 2019 Report has been prepared in accordance with the GRI Standards: Core option.

### VIEW OUR NOVARTIS IN SOCIETY 2019 REPORT:

→ [www.Novartis.com/sites/www.Novartis.com/files/Novartis-in-society-report-2019.pdf](http://www.Novartis.com/sites/www.Novartis.com/files/Novartis-in-society-report-2019.pdf)

