

Novartis in Society 2020 US Report





Contents

2020 HIGHLIGHTS	3
FOREWORD	4
CORPORATE RESPONSIBILITY	5
SCIENCE AND INNOVATION	9
VALUE AND PRICING	12
PATIENT ACCESS	14
RESPONSIBLE BUSINESS PRACTICES	16
ABOUT NOVARTIS	19



2020 Highlights

15 942

Full-time equivalent employees in the US of whom 5 554 are employed at our US-based R&D sites

USD 2.9 BN

Invested in R&D in the US, representing 32% of our global R&D spend that totaled USD 9.0 billion

3

Major regulatory approvals received by Novartis in 2020

348 658

Patients received support through our co-pay assistance program in 2020

363 553

Patients received free medication valued at over USD 10.5 billion through the NPAF over the past five years

Foreword

This has been an extremely challenging year for people and societies everywhere. The COVID-19 pandemic has caused suffering on a global scale not seen in more than a century, with long-lasting repercussions. For Novartis, the crisis has given added urgency to our purpose of reimagining medicine to improve and extend people's lives. And it has inspired us to find new ways to help patients, strengthen communities and foster sustainability.

This also has been a time of hope and resilience, as we accelerated efforts to develop innovative treatments for serious diseases and conditions and meet patient needs. When the COVID-19 crisis hit, Novartis immediately mobilized to protect our associates and their families, along with the thousands of individuals participating in our clinical trials. We also moved decisively to secure our supply chains and ensure patients would continue to receive our medicines and treatments.

Early in the pandemic, we assembled a task force to examine our entire portfolio for potential treatments for COVID-19, and we pursued clinical studies that helped to improve the scientific understanding of the disease. The crisis has spurred an unprecedented level of collaboration both inside Novartis and across the pharmaceutical industry, with individuals, teams and businesses using their collective innovation power and global commitment to end the pandemic as quickly as possible.

COVID-19 has underscored the pressing need to make healthcare more equitable, responsive, accessible and affordable for patients. Novartis understands this and, more importantly, is doing something about it.

For example, we are taking bold and creative actions to address the under-

representation of minorities in clinical trials, which are key to the development of innovative medicines. Greater diversity in clinical trial participation can help us build a more equitable and responsive healthcare system benefitting all members of society. Separately, the Novartis US Foundation has made disparities of care a priority issue as part of its broader commitment to driving greater health equity in the United States through strategic partnerships at the national and local levels.

Questions of equity, fairness and inclusion were at the heart of racial justice protests in the US and elsewhere this past summer, and Novartis felt it was critically important to help our associates and leaders confront these issues openly and honestly. Last September we held our first-ever Day of Reflection, encouraging our US-based associates to learn, think and talk about what it means to be part of a truly diverse and inclusive organization. That event – which we plan to hold every year – reflected our strongly held belief that at its core, equality is a human rights issue.

We also see diversity and inclusion as essential to delivering on our purpose as a healthcare company. We are embedding diversity principles deep in our company culture and constantly looking for ways to reinforce this commitment, including through policies in recruiting, retention and promotion to leadership roles.

Looking ahead, we see exciting new opportunities to deliver even more for patients, and to help rebuild lives and communities. We all have learned important lessons about the need to improve access, build trust and reach out to people in need. At Novartis, we are finding new ways to advocate on behalf of patients, further environmental sustainability in our operations, and strengthen and



Thomas Kendris

protect our access programs. We also rolled out a new Code of Ethics to help us do what's right for patients, society and our company. You can read more about these and other initiatives in this report, and I welcome your comments and suggestions.

We look forward to continuing to work closely with all our partners and stakeholders as – together – we build a strong and sustainable healthcare system for the future.

Sincerely,

Thomas Kendris
US Country President

**WE WELCOME YOUR
FEEDBACK:**

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

Corporate responsibility

Corporate responsibility is endorsed and ingrained at the highest level of Novartis and is central to the way we run our business. Our corporate responsibility strategy supports the Novartis purpose and is centered around four key areas: holding ourselves to high ethical standards, being part of the solution on pricing and access to medicines, helping tackle global health challenges, and being a responsible global citizen.

Diversity & Inclusion

Novartis strives to adhere to high standards of diversity and inclusion (D&I) in our culture and values, as embodied in our company's new Code of Ethics. We believe this helps drive innovation, generates new ideas, and brings us closer to patients and other stakeholders. Our D&I principles – built around equity, inclusivity and society – empower our associates to do what's right in making decisions and taking actions.

We are making progress towards our United Nations (UN) Equal Pay International Coalition pledge to achieve gender balance in management and further improve pay equity and transparency processes by 2023. The percentage of women managers in our US business rose to 47.5% in 2020, and by February 2021 we will have introduced pay transparency in 16 countries, including the US.

We continue to move forward with important D&I initiatives in the US to build and reinforce our positive culture. These include cultivating a diverse and equitable environment for our associates, supporting and retaining diverse talent, strengthening and empowering Employee Resource Groups and Councils, and shaping society.

For example, we developed and launched a Multicultural Engagement Program to strengthen and retain our



diverse talent and pave the way for them to assume critical leadership roles in the future. Through this program, we are providing direct one-on-one coaching, training and executive mentoring. We also established new hiring guidelines that require gender and ethnic/racial diversity in our candidate slates and on interview plans, and hired a D&I talent acquisition team to help us identify and attract diverse talent to the company.

As part of our work to help shape society, Novartis was the first major pharmaceutical company to support the UN's LGBTI Standards of Conduct, which seek to end discrimination against lesbian, gay, bisexual, transgender and intersex people in the workplace. We also committed to increase patient diversity within our clinical research and development programs, launched Disparities in Care initiatives, and implemented a Diverse Supplier Protocol to deepen our partnership with women-, minority-, veteran- and LGBTQ-owned businesses.

Our D&I achievements continue to be recognized outside the company. We maintained our status as one of seven 2020 DiversityInc Hall of Fame companies and have been ranked number one in our industry in the 2020 Refinitiv Diversity & Inclusion Index for the second consecutive year. We also scored 100% on the LGBT Corporate Equality Index of the Human Rights Campaign and were named a Military Friendly Employer for 2020 by Victory Media, publisher, GI Jobs Magazine.

Standing Together against injustice

In the wake of social justice movements in the US and elsewhere in 2020 following the murder of George Floyd and other needless tragedies, Novartis provided tools and resources for our associates to help provide perspective and knowledge and to empower them to Stand Together against injustice. Novartis states emphatically that the company has zero tolerance for racism or bias of any kind. We believe unequivocally that Black lives matter.

Novartis also developed new ways to reinforce this commitment and demonstrate solidarity around the principles of equality, diversity and inclusion. We held a Juneteenth program with more than 4 800 associates, focused on understanding the history and current impact of, and future solutions to, racial equity issues.

In September, Novartis hosted the company's first-ever Day of Reflection, virtually bringing together 6 700 associates to learn, think and talk about what it means to be part of a truly diverse and inclusive organization. The deeply personal sessions were hosted by senior Novartis leaders, and designed to help associates understand the importance of going beyond supporting equal rights to actively working against hatred and inequality everywhere.

Associates responded enthusiastically to the Day of Reflection, with 93% of participants saying they gained a better understanding of the company's actions to create a diverse and inclusive envi-

ronment, and 89% agreeing they could apply learnings from the Day of Reflection to help create an inclusive and positive environment at work. Novartis plans to make the Day of Reflection an annual event in the US, to be held on or around the Juneteenth holiday.

In addition, we continue to provide inclusive culture training, programming and resources on an ongoing basis. In line with this commitment, the Novartis US Foundation has donated to programs and supports community and advocacy group initiatives focused on health equity and racial justice.

Novartis US Foundation

Novartis US Foundation fosters strategic partnerships and innovative programs to drive greater health equity in the United States. We believe that all people – regardless of race, age, sex, socioeconomic status, or geography – should have an opportunity to achieve their best possible health.

The US Foundation seeks to advance sustainable change through initiatives to build trust between patients and healthcare providers, expand healthcare access, and address social determinants of health in local communities. We establish partnerships and support programs to:

- increase diversity in the healthcare workforce and address implicit bias within health systems;
- improve access to healthcare services for vulnerable populations through innovative solutions that reduce barriers to care; and
- provide aid and support to address social determinants of health in the communities where we work and live.

Since 2019, the US Foundation has provided more than USD 12 million to programs and initiatives in these areas. One of our signature partnerships is with the Institute for Healthcare Improvement in support of their Pursuing Equity initiative, which brings together a variety of healthcare organizations to determine, share and advance new solutions to drive measurable change within the healthcare system.

As part of our ongoing commitment to Diversity & Inclusion, we are committing to publicly disclose our consolidated US EEO-1 information following its submission to the US Equal Employment Opportunity Commission in April 2021. This is a government-required submission filed by all companies with 50 or more employees in the US that provides demographic information related to gender, race and ethnicity of a company's US employee population. It can serve as an important benchmark against which future progress on D&I efforts can be assessed. While the content of an EEO-1 filing has historically not been made public, we will make this information available on our website once our EEO-1 submissions for 2019 and 2020 are filed in or about April 2021.



COVID-19 relief

With COVID-19 profoundly impacting US families and communities in unprecedented ways, Novartis and the Novartis US Foundation moved quickly to establish a US COVID-19 Community Response Fund, providing cash and in-kind donations for immediate response and recovery efforts related to the pandemic. The Fund has provided grants to 40 community organizations to support local response efforts.

Our focus on addressing health equity and barriers to access proved timely, as telehealth became a crucial lifeline for patients during COVID-19. Our pre-pandemic support for the New Jersey Primary Care Association enabled five New Jersey Community Health Centers to quickly launch telehealth programs after the pandemic began. Despite dramatic drops in patient volume due to COVID-19, pilot centers were able to maintain continuity of primary and specialty care services for some of the state's most vulnerable populations.

To provide additional resources for communities impacted by COVID-19, the US Foundation instituted a limited-time, two-for-one match to amplify Novartis associates' support for national and local organizations working on the frontlines during the pandemic. This campaign provided nearly USD 850 000 in

combined associate donations and US Foundation match contributions. In the first weeks of the pandemic, we also partnered with YouGiveGoods, an online platform for employee donations of goods, to provide more than USD 46 000 of food and needed supplies to community-based organizations across the country.

Social justice response

The US Foundation responded to increased national attention on social justice issues in 2020 by providing funding to the NAACP Empowerment Programs for core health equity programming. Our associates also supported social justice causes through a special match campaign, which raised more than USD 110 000 in combined employee and Foundation donations.

In addition, the US Foundation announced a longer-term commitment of USD 15 million to address health equity with a focus on the lack of diversity in clinical trials. We plan to identify and convene potential collaborators from the public, private and advocacy sectors to consider solutions to this challenge, including ways to address social and systems-based issues related to minority participation in clinical trials.

LEARN MORE ABOUT RECIPIENTS OF COVID-19 COMMUNITY RESPONSE FUND GRANTS

→ www.novartis.us/news/novartis-us-covid-19-initiatives/novartis-us-foundation-provides-support-40-community

LEARN MORE ABOUT NOVARTIS AND OUR IMPACT ON PATIENTS, FAMILIES AND THEIR COMMUNITIES

→ www.novartis.us/about-us/novartis-us-glance

→ www.novartis.us/corporate-responsibility



Associates making a difference

Novartis associates are generous donors to a wide range of charities and causes, committing both time and financial resources to efforts to improve health, strengthen communities and build trust. In 2020, associates donated nearly USD 1.5 million through the Matching Gifts Program to nonprofit organizations of associates' choosing, beyond the COVID-19 and social justice causes.

While associate volunteering shifted from in-person to virtual activities due to the pandemic, the company continued to support these efforts through volunteer time off and volunteer recognition grants. We continued our successful mentorship programs and initiatives, including the Independent College Fund of New Jersey's Novartis Science Scholarship awards, with Novartis scientists providing yearlong mentoring to undergraduates conducting independent science research.

Environmental sustainability

At Novartis, we believe environmental sustainability is directly tied to the sustainability of our business. Our continued investment in our planet supports our purpose to improve and extend people's lives and helps us build trust with society. We want to be a leader in environmental sustainability and a catalyst for positive change, driving sustainability through our own operations and ultimately across our

value chain, and advocating for strong sustainability policies across our industry and society.

Our long-term strategy sets ambitious targets in climate, water and waste for 2025 and 2030, building on our current achievements in these areas. Realizing these goals will enable our business to be carbon-neutral and energy and climate resilient; support the creation of a circular economy by being plastic neutral, minimizing waste and increasing material efficiency; and be water neutral by ensuring sufficient and safe water, and operating as a good water steward.

For example, to help reduce waste, Novartis redesigned the sample packaging for *Entresto*, one of our cardiovascular treatments. Previously it was packaged using two bottles in a carton with a leaflet. Now we are starting to use a single bottle with no carton, and the leaflet attached to the side of the bottle.

Novartis aims to be carbon neutral in its operations by 2025. Our virtual power purchasing agreement with the Santa Rita East windfarm in Texas is helping to achieve this goal. In 2020 the windfarm produced 417 000 megawatt hours of carbon-free electricity, which is the equivalent of powering 481 000 average American homes for one year.

Our Global Drug Development organization also is focused on climate impact, launching a pilot program that includes carbon pricing and impact

into early-stage development of future drugs. This helps us make better decisions earlier about ways we can reduce carbon emissions during scale-up of new products.

Novartis has engaged in educating policymakers on our efforts related to environmental sustainability, including supporting carbon-pricing efforts in the states, renewable portfolio standards, climate resilience and justice, and adoption of zero- and low-emission vehicles. Building on our work in 2019, we have continued outreach on environmental issues, including signing a letter of support for the Transportation Climate Initiative to deliver cleaner transportation for 12 states on the East Coast.

To strengthen our ongoing engagement with policy leaders on sustainability issues, we recently joined the Business for Innovative Climate and Energy Policy (BICEP) network, a diverse coalition of global enterprises advocating for sound sustainability policies with governments and other organizations. Novartis has informally supported BICEP and its sponsor, Ceres, with participation in multiple advocacy meetings with lawmakers and staff in the last two years, and will continue to do so as a formal member of the organization.

We look forward to enhancing our efforts in 2021.

Science and innovation

Our 5 500 US-based scientists and other research and development professionals are using innovative tools and technologies to challenge medical paradigms, exploring new possibilities to cure disease, intervene earlier in chronic illnesses, and find ways to improve quality of life.

The Novartis purpose is to reimagine medicine to improve and extend people's lives. We continued to deliver transformative innovation for patients in 2020, including approvals in the US and worldwide for multiple sclerosis, non-small cell lung cancer, and other serious disorders.

COVID-19 response

The COVID-19 pandemic provided a stark reminder of the impact of disease on individuals and societies, highlighting the urgent need for science-based solutions.

The scale and scope of our research and development (R&D) operations provided the foundation for our robust response to the pandemic. As the crisis unfolded, we convened a task force to look at our entire portfolio and examine every molecule for potential treatment of patients with COVID-19 as well as to determine how to protect the integrity of ongoing clinical trials.

We quickly designed and launched three Phase III, placebo-controlled trials to test promising hypotheses. One study was stopped early due to enrollment challenges. Although the other two studies showed negative results, they helped to improve the scientific understanding of the disease. We are also collaborating with Molecular Partners to develop two potential antiviral treatments for COVID-19 based on a new class of protein therapeutics known as DARPIn®.

We collaborated with other companies and academic and non-profit organizations in open-science efforts to identify immediate solutions for patients and anticipate pandemics of the future. For example, we are working with researchers from the University of California, Berkeley, and others in an effort to find a molecule that blocks all coronaviruses, including the virus that causes COVID-19.

In parallel, we took steps to safeguard clinical trial participants as well as our own associates. New processes and technologies – including systems that enable remote monitoring of clinical trials – have proved crucial for protecting patients and our people in drug development, allowing us to advance promising treatments in a variety of disease areas during the crisis. More than 35 000 remote monitoring visits took place from March to the end of the year.

A new digital recruiting platform for studies also proved useful during the pandemic. It leveraged social media channels to inform patients or healthcare providers about trials that might be of interest to them. Potential participants could choose to visit a website, complete a brief screening questionnaire, and be contacted by a call center for more information. By the end of the year, the full platform had launched and generated more than 140 pre-qualified leads to sites for three clinical trials, including a pivotal Phase III study.

Data science and digital technologies

For the last few years, our teams have been working to integrate and leverage massive amounts of data at Novartis, using new tools and platforms and also deploying cutting-edge digital technology across the organization. We continued to advance our priorities in this area despite the pandemic.

For example, we convened a team of experts to evaluate and prioritize data and digital opportunities for key assets. Take CFZ533 (iscalimab), an experimental immunomodulatory therapy with the potential to make kidney and liver transplants, which are often rejected by the immune system, durable. The Novartis team proposed using an algorithm to get an early indication of the compound's effectiveness by determining the health of the transplanted organ with the goal of predicting its survival. We are collaborating with external academics to develop the algorithm using lab test and biopsy results from patients.

We are bringing important new digital capabilities into Novartis. In April, we acquired Amblyotech, a US-based software startup that will help us develop an innovative digital technology for the treatment of amblyopia, also known as "lazy eye". Amblyotech utilizes active gaming and passive video technology with 3-D glasses, training the eyes to work together to view an image in

whole. The acquisition expands our refractive disorder pipeline in ophthalmology.

Advanced therapy platforms

A key part of our R&D strategy is to pursue new approaches to treating disease, such as by using genes and therapeutic viruses. One of our leading gene therapy platforms employs benign adeno-associated viruses (AAV) to deliver genes to cells inside the body, with the goal of repairing cells with a one-time treatment.

In 2019, our AAV-based therapy *Zolgensma* – part of our recently re-named Novartis Gene Therapies unit – was approved in the US for certain patients with a devastating neurodevelopmental disease called spinal muscular atrophy (SMA). We maintained momentum in 2020 by launching the drug in additional markets and continuing our efforts to develop an intrathecal formulation for use in older SMA patients.

Another gene therapy platform involves a set of programmable molecular ‘scissors’ called CRISPR, or clustered regularly interspaced short palindromic repeats, which can permanently change cells by snipping the DNA that’s found deep inside them at precise points. We’re developing a potential treatment for sickle cell disease with CRISPR technology licensed from Intellia Therapeutics. In 2020, patients began enroll-

ing in a small clinical trial designed to test the treatment. It’s a gene therapy, but it’s also a cell therapy because cells are removed from the body and modified in a lab to generate the drug.

All of this work builds on our early successes with chimeric antigen receptor T-cell (CAR-T) therapy. Our flagship CAR-T therapy, *Kymriah*, was the first gene therapy approved in the US. It’s also a cell therapy: a patient’s T cells are extracted and reprogrammed to recognize and fight cancer cells before being infused back into the body.

We’re designing new CAR-T therapies and exploring how to overcome resistance and relapse in a variety of difficult-to-treat cancers. We’re also piloting a new manufacturing platform that has the potential for higher efficiencies, shorter turnaround times and better outcomes. Our experimental treatments YTB323 and PHE885, manufactured using our innovative platform technology, recently entered clinical testing. In parallel, we’re optimizing the manufacturing process for *Kymriah*.

Another important platform is radioligand therapy, a targeted approach using radioactive atoms that has the potential to become a pillar of cancer treatment. Our leading radioligand treatment *Lutathera* – which is marketed by a Novartis company called Advanced Accelerator Applications – is approved for certain gastroenteropancreatic neuro-

endocrine tumors, which are rare. Teams are now testing the approach in more common cancers. For example, our experimental treatment ¹⁷⁷Lu-PSMA-617 is currently in a pivotal clinical trial for an advanced form of prostate cancer. We expect to report results in 2021.

We’re also exploring ways to use RNA-targeting therapeutics to treat disease. These molecules recognize and initiate the degradation of mRNA, which carries instructions for protein synthesis from DNA, thereby blocking the production of specific proteins thought to be involved in causing disease.

We are pursuing FDA approval to market a small interfering RNA molecule called inclisiran for the treatment of hyperlipidemia, a common condition that increases the risk of heart disease. Three large clinical trials demonstrated that it significantly reduces LDL cholesterol in patients with the condition. Inclisiran was licensed from Alnylam Pharmaceuticals, Inc., and developed in collaboration with The Medicines Company, which Novartis acquired in early 2020.





Pipeline progress

Our focus on cutting-edge treatments for serious diseases extends to our assets in full clinical development. We are advancing more than 160 projects, with more than 40 pipeline assets in full development, and including more than 25 potential blockbuster medicines.

Our mid-stage portfolio deserves particular attention, with a number of compounds that have the potential to change the course of intractable illnesses. Take osteoarthritis, which affects more than 300 million people worldwide and is the leading cause of disability in adults due to degeneration of cartilage in the joints. Existing treatments focus on relieving symptoms rather than altering the progression of the disease. LNA043, discovered in our own labs, has the potential to protect and repair cartilage in the joints of patients with osteoarthritis. We are currently testing the experimental treatment in patients with knee osteoarthritis.

Other molecules born in our labs have the potential to transform the treatment of rare diseases. For example, we're studying LMI070 (branaplam) in Huntington's disease and SMA. Our investigational oral therapy iptacopan (LNP023) is being studied in several rare complement-driven diseases, and received FDA Breakthrough Therapy Designation for paroxysmal nocturnal hemoglobinuria and Rare Pediatric Disease Designation for C3 glomerulopathy.

Our teams continually challenge treatment paradigms and build on the success of established franchises. For example, our neuroscience researchers are working to develop targeted treatments that can significantly improve outcomes for patients with multiple sclerosis, a disease that we have worked on for decades. In August, the FDA approved *Kesimpta* (ofatumumab), the first and only self-administered, targeted B-cell therapy for patients with relapsing multiple sclerosis.

40+

pipeline assets in full development

~90%

Novartis treatments in development are first in class or first for a specific medical indication

Value and pricing

Novartis is a leading voice calling for the fundamental transformation of our healthcare system. We want to transition to a system that is more accessible for all patients and uses value and outcomes criteria to determine how treatments are priced and reimbursed. With so many innovative medicines in development and in the clinic – including potentially curative cell and gene therapies for some diseases – Novartis is taking action now to drive systemic change and improve affordability and access.

Novartis believes that we should base the pricing of medicines on the value they deliver to patients, to science and medicine, and to society as a whole. As an example, clinical and patient outcomes, along with cost offsets from reduced hospitalizations, have played an important role in the way Novartis has priced *Entresto*, our novel treatment for reduced ejection fraction in patients with heart failure.

A value-based approach to healthcare incentivizes the healthcare sector to focus on the therapies that deliver the most effective, efficient and sustainable outcomes. In the US, we currently have value-based agreements in place for several of our key innovative medicines including *Zolgensma*, a revolutionary new gene therapy to address the root cause of spinal muscular atrophy in newborns and infants; *Cosentyx*, for moderate to severe plaque psoriasis; *Kymriah*, an individualized therapy for certain types of advanced blood cancers; and *Entresto*.

Novartis also was among the first pharmaceutical companies to enter into outcomes-based contracting for certain medicines, which links reimbursement rates to specific clinical outcomes. This approach reduces some of the financial risk for patients and payors when they access newer treatments covered by these contracts.

Value-based pricing and access

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 work to make our medicines available by considering both effective affordability strategies and innovative solutions. We aim to price our new medicines based on the value they deliver to patients, healthcare systems and society. For example, cost offsets from prevented hospitalizations have played an important role in the way our treatment for heart failure is priced.

Novartis is expanding our commitment to value-based models of care by calling for a system shift that links drug pricing and patient access to the value they provide patients.

Under this approach, drug manufacturers offer a value-based price and in turn, payors do their part by providing streamlined access to these medicines for patients. Everyone stands to benefit: patients have easier access to the medicines they need; providers spend fewer hours navigating insurer requirements; insurers pay less for drugs and need fewer systems to manage access;

and biopharmaceutical companies can focus on researching and commercializing the most innovative treatments.

Novartis believes all of us in healthcare must come together to demystify the current complex system and recognize that fundamental change is necessary. Ultimately, we want to join forces with stakeholders across the drug supply chain to build a new and more sustainable value- and access-oriented healthcare system for the future.

US pricing principles

At Novartis, we price our medicine according to a value-based framework that provides an analytical basis for our pricing decisions. Across our branded products, we limit our portfolio net price increases to at or below the National Healthcare Expenditures rate as determined by the US Centers for Medicare and Medicaid Services. We also do not take price increases for branded products that have an available generic equivalent.

Generics and biosimilars

Through our Sandoz division, we are delivering high-quality generic medicines and biosimilars to clinicians and patients. In 2020, Sandoz launched several medicines that expanded our hospital portfolio, including critical treatments

US product portfolio¹ – % change vs prior year²

	2016	2017	2018	2019	2020	5 year average
Total gross price change³	6.2%	5.4%	5.6%	4.9%	3.7%	5.2%
Total net price change⁴	-2.0%	-2.1%	-1.1%	2.9%	-0.2%	-0.5%

- ¹ US product portfolio for 2016 to 2020 includes all medicines sold by the US Innovative Medicines Division, including Alcon Ophthalmics products as applicable, medicines sold by AAA, Novartis Gene Therapies, and the US Sandoz Division.
- ² 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.
- ³ 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.
- ⁴ 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.

92%

of prescriptions in the US are generic drugs

	2016	2017	2018	2019	2020
Total US rebates and discounts^{1,2}	-47.7%	-49.5%	-49.8%	-48.4%	-46.8%

- ¹ Total US rebates, discounts and deductions calculated as a percentage of total gross sales.
- ² 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.

-46.8%

the total annual rebates and discounts on Novartis products

for patients with COVID-19 symptoms, including Dexmedetomidine Hydrochloride Injection, Kitchick Anectine, and Kitchick Norepinephrine. We also took early action to ensure that patients could access our full portfolio of products during the pandemic, including maintaining stable prices on 23 essential medicines for the treatment of COVID-related symptoms and disease complications.

Generics and biosimilars provide significant cost savings to individuals and the broader healthcare system. A good example of this is our cancer treatment-related therapy *Zarxio* (filgrastim-sndz), which was the first biosimilar approved

by the FDA in 2015. Over the past four years, filgrastim generated approximately USD 1.2 billion in savings to the US healthcare system, with *Zarxio* driving the majority of the market.

Prices of US generics continue to decrease year over year, and while generic drugs represent 92% of prescriptions dispensed in the United States, they account for only 20% of overall national drug spending. In 2019 alone, the US generics industry contributed more than USD 313 billion in savings, with Sandoz medicines accounting for USD 12.1 billion.

KEY CORPORATE PUBLICATIONS:

→ www.novartis.com/news/publications

Patient access

The Novartis Commitment to Patients and Caregivers obligates us to do all we can to expand patient access to our medicines and treatments. It also commits us to understand the patient community perspective, conduct responsible clinical trials, and recognize the importance of transparency and reporting.

Promoting greater participation in clinical trials

The development of new medicines is a lengthy and complex process that depends greatly on patients volunteering to participate in clinical trials. These trials evaluate the safety and efficacy of treatments and are a vital step in their regulatory approval and availability to patients. It is critically important to have broad-based participation in clinical trials to help researchers find better ways to fight diseases, including those that disproportionately affect certain populations.

For the past several years, Novartis has been developing and implementing new approaches to make it easier for people to be part of clinical trials. More recently, the onset of the COVID-19 pandemic required us to move quickly to ensure that important trials could proceed. For example, we are using telemedicine and virtual visits to trial sites so patients can safely continue to participate in trials. We also are using smartphone technology to recruit for trials, meeting patients where they prefer to interact with us – in person or online – and looking for new ways to address their medical concerns.

Thanks to new digital technologies, we are better able to assess health and learn more about how patients are doing, not only in terms of their disease or condition, but also in their quality of life. We expect to use and expand these new approaches even after the pandemic ends.

Improving diversity and inclusion in clinical trials

Currently, certain important populations are significantly underrepresented in clinical trials, and this lack of diversity is contributing to disparities in care among minority groups. The COVID-19 pandemic has shined a spotlight on this issue and created a call to action for change.

Novartis is active on a variety of fronts to further greater diversity and inclusion in clinical trials. For example, we are pursuing partnerships and other strategic relationships to enhance trial accessibility and expand our geographic reach. These include exploring alternative recruitment models and aligning with trial centers and local hospitals in densely populated areas with diverse patient groups, with the goal of expanding trial locations. We also are embedding diversity considerations along a broad continuum from early in a drug's development, to protocol-writing and site selection for clinical studies, to tailored candidate recruitment strategies.

Leveraging our leadership in data and analytics, Novartis is using technology to expand outreach and recruitment for clinical trials as well as democratize access to care. We are employing artificial intelligence to assess 2 million patient-years of clinical studies data with the aim of better managing disease and understanding differences in patient outcomes among different groups.

With this information, we plan to develop a number of new initiatives and models, including an inclusive gender health-equity strategy.

In addition, Novartis US Foundation is making a USD 15 million commitment to explore health inequities with a focus on addressing the vast underrepresentation of minorities, including Black Americans, in clinical trials. The US Foundation plans to identify and convene potential collaborators from the public, private and advocacy sectors to ignite a targeted, progress-driven effort to drive change around diversity in clinical trials.

Patient access programs

Assistance programs are critical for helping patients access healthcare when it is unaffordable. Even when patients have insurance coverage for drug prescriptions, some still might be unable to afford certain medications.

Novartis Patient Assistance Foundation (NPAF) provides medicines at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage. In 2020, NPAF provided more than USD 3.3 billion in free medicines to more than 107 000 patients, covering 72 medicines from our portfolio. Over the last five years, medication valued at roughly USD 10.5 billion has been made available to 363 553 patients.



In 2020, NPAF began providing access to new Novartis medicines, including *Tabrecta*, for a type of metastatic non-small cell lung cancer; *Kesimpta*, for relapsing multiple sclerosis; and *Ziextenzo*, for patients receiving chemotherapy who are at risk of infection.

With COVID-19 presenting significant new challenges to the healthcare system, NPAF adapted quickly to ensure that patients continued to receive their medicines. Due to quarantine and travel restrictions, patients faced difficulty in submitting documentation for NPAF eligibility, while healthcare providers, who collect patient NPAF enrollment documents, had restricted access to their

patients. Many patients also experienced job loss and financial difficulties.

In response, NPAF took measures to reduce the additional burden on patients and healthcare providers, working to ensure continuity of treatments. This included modifying processes for gathering and reviewing documentation, expanding timeframes for prescription renewals, and shipping patients a longer supply of medicines.

Novartis also 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, employer or laws. Due to current regulations, co-pay assistance is not available to patients covered by government healthcare programs, such as Medicare and Medicaid.

Responsible business practices

A key strategic priority for Novartis is to build trust with society. We do this by operating with strong values and integrity and by finding new ways to deliver our treatments to as many people as possible. Our commitment to responsible business practices is central to our vision of becoming the most valued and trusted medicines company in the world.

Code of Ethics

In 2020, Novartis unveiled a new Code of Ethics, building on our existing Code of Conduct and Professional Practices Policy. Covering all associates worldwide, the Code of Ethics helps us to ensure that we do what's right for patients, society and Novartis. It enables our associates to make decisions that are aligned with our values and ethical principles, and encourages open dialogue around the challenges we face in our day-to-day efforts to reimagine medicine.

Our code calls on us to be open-minded, honest, bold and accountable. Each of these principles is accompanied by a set of questions that associates should ask themselves as they go through the decision-making process. They include: Am I actively listening to ideas or concerns? Am I acting with clear intent? Am I standing up for what I believe? Am I taking responsibility for my decisions? The code is accompanied by a decision-making framework that helps associates challenge their intuition and encourages reflection on the potential impact of their decisions.

Demonstrating our commitment to fostering an unbossed and empowered culture, Novartis encouraged associates

worldwide to help develop the code's framework and language, with more than 3 000 of them participating. Their involvement reflects a widely held belief inside our company that doing the right thing is central to our purpose of reimagining medicine to improve and extend people's lives.

Advocating for patient access and affordability

Novartis is committed to engaging with elected officials and regulators as we seek sustainable solutions to advance patient health and strengthen our healthcare system. In fact, the vast majority of our interactions with government officials relate to issues of access, affordability and sustainability around medical treatments. Specifically, we want to increase opportunities for patients to access our medicines, reduce patient out-of-pocket costs for therapies, and promote a sustainable healthcare system for all. This requires ongoing dialogue with policymakers and regulators who play a central role in shaping our healthcare system.

A good example of this is our work to make our breakthrough gene therapy *Zolgensma* more widely available to patients. Following the drug's approv-

al in the US in 2019 for spinal muscular atrophy (SMA) in patients less than two years old, we knew it was vital for families to learn as quickly as possible if their children had SMA so they could gain access to this lifesaving treatment. To that end, we partnered with patient advocates and healthcare providers to make the case for states to include SMA in newborn screening panels. More than 30 states are now screening newborns for SMA or have committed to do so soon. We continue to work with policymakers to extend SMA screening in the remaining states, plus the District of Columbia and Puerto Rico.

The ability of patients to access medicines is directly tied to reimbursement policies by private insurers and government payors, such as Medicare and Medicaid. Novartis works closely with public and private payors to advocate for inclusion of our medicines on approved formularies. Partnering with internal colleagues, we were successful in securing Medicaid access for *Adakveo*, which will make this advanced therapy for Sickle Cell Disease widely available to a broad patient population in need. We also continue to work with state Medicaid officials to ensure access for *Zolgensma* that is consistent with FDA-approved labeling.



Company-provided co-pay cards help thousands of patients afford their medicines and Novartis is working vigorously to protect this program. We are supporting state-level legislation that limits a health plan's ability to restrict the use of co-pay cards, and are calling for reforms to allow patients to benefit from rebates, which are currently provided by pharmaceutical companies to health plans.

Lobbying reporting

Federal and state laws dictate what falls under lobbying in terms of expenditures, reporting and registration, and this is

further clarified through guidance from the United States Senate and United States 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. Included in the amount disclosed are labor hours of all Novartis associates 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. We make financial political contributions only in countries where such contributions are 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 and political action committee funds are permissible by state law and otherwise considered appropriate.



In 2020, Novartis made political contributions totaling USD 982 250 in the US. This figure includes:

- Contributions to state-oriented political groups, as permitted by state law (USD 325 000¹);
- 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 (USD 433 250²) 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 199 000³).

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

→ clerk.house.gov/public_disc/index.aspx

→ soprweb.senate.gov/index.cfm?event=selectfields

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

² This number represents the total amount of pledged political contributions in 2020, though the actual value of contributions given could be smaller due to the changing nature of campaigns and other administrative issues.

³ As of December 31, 2020 – Federal Election Commission report

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 nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110 000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

In the US, Novartis has nearly 16 000 full-time equivalent employees in skilled positions across 21 locations. We have six headquarter campuses: East Hanover, Millburn and Princeton, New Jersey; Cambridge, Massachusetts; Indianapolis, Indiana; and Bannockburn, Illinois.

ESG reporting at Novartis

Novartis has a strong history of reporting on environmental, social and governance (ESG) topics. We are committed to taking real, measurable and reportable action in these key areas, and making sure that we communicate about them clearly and transparently.

For the eighth consecutive year, Novartis is publishing an annual Novartis in Society ESG report (formerly our Corporate Responsibility Report), which details our progress against our targets. The 2020 Report has been prepared in accordance with the Global Reporting Initiative (GRI) Standards: Core option.

**VIEW OUR GLOBAL
NOVARTIS IN SOCIETY
ESG 2020 REPORT:**

→ [www.reporting.novartis.com/
novartis-in-society.html](http://www.reporting.novartis.com/novartis-in-society.html)

