

Contents

FOREWORD	4
BEACON OF HOPE	6
CORPORATE RESPONSIBILITY	9
SCIENCE & INNOVATION	14
/ALUE AND ACCESS	19
RESPONSIBLE BUSINESS PRACTICES	22
2021 AT A GLANCE	24
ABOUT NOVARTIS	27



2021 Highlights

14890

Full-time equivalent employees in the US of whom 5 250 are employed at our US-based R&D sites

USD 3.17 BN

Invested in R&D in the US, representing 33% of our global R&D spend that totaled USD 9.54 billion

8

FDA approvals, including new indications

320 450

Patients received support through our co-pay assistance program in 2021

445000

Patients received free medication valued at over USD 13.5 billion through the Novartis Patient Assistance Foundation over the past five years

49%

Women in Novartis US management

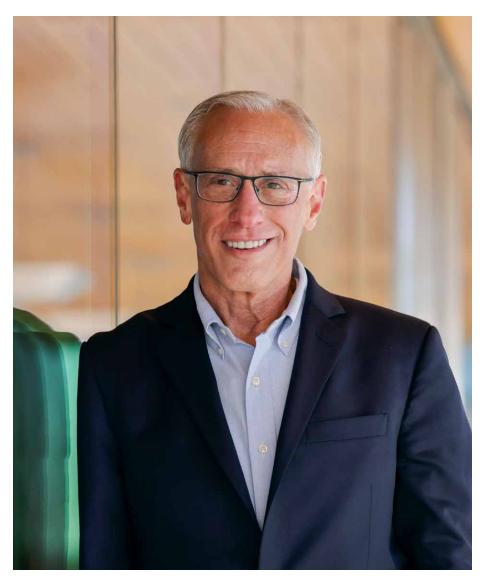
Foreword

Novartis takes a broad view of our purpose to reimagine medicine to improve and extend people's lives. Discovering and developing innovative treatments is at the core of this commitment, but so is furthering access to quality healthcare, including by fostering greater diversity, inclusion and equity in our healthcare system.

COVID-19 is a stark reminder of the harmful effects of health and social disparities, especially in the United States, where racial barriers and historic inequities continue to place an enormous burden on individuals and communities alike. But the pandemic also has provided fresh impetus for us to work together to make systemic changes that can put us on a path toward better health and greater opportunity for all.

In the US, much of our focus in 2021 has been on building strong engagement with health and education systems as well as patient and community organizations that share our goals to further health equity. We are developing and implementing sustainable solutions to address the root causes of disparities and inequities, using new tools, approaches and perspectives to drive meaningful change.

A good example of this is our Beacon of Hope initiative, which we launched last July to directly confront the systemic racism behind inequitable health outcomes in the US. This novel ten-year collaboration involving 27 Historically Black Colleges and Universities and other organizations aims to instill greater diversity and inclusion across our healthcare ecosystem. Our commitment of USD 33.7 million - through our company as well as the Novartis US Foundation - will fund scholarships and other educational programs for Black and African American students, along with other research focused on underserved minority populations.



"At Novartis, we reimagine medicine in the broadest possible sense, from finding innovative treatments that improve and extend people's lives, to making our healthcare system more accessible and equitable for all. We put special emphasis on developing sustainable solutions that address the root causes of healthcare disparities and inequities, using new tools, approaches and perspectives to drive meaningful change."

Thomas Kendris, President, Novartis Corporation & US Country President

Beacon of Hope builds on ongoing company and US Foundation initiatives in health equity that also were expanded in 2021. These include efforts to increase minority participation in clinical trials – a critical step in addressing disparities in care at the population level – as well as targeted programs in cardiovascular disease, breast cancer and sickle cell disease, all of which disproportionately affect communities of color.

Acting as a responsible corporate citizen is critical to achieving our purpose as a healthcare leader. Our approach to corporate responsibility closely aligns with established environmental, social and governance (ESG) criteria, which are reflected in our programs in diversity & inclusion, health equity and environmental sustainability – areas where Novartis is striving to be a catalyst for systemic change.

Our healthcare system continues to be challenged by the evolving needs of a growing and aging population. At the same time, the future of medicine has never looked brighter, with novel and potentially curative therapies bringing new hope for many patients. As a result of these trends, value and access remain center stage in today's healthcare policy debates. Novartis has a strong voice in these discussions, advancing proposals to broaden access to medicines, move toward value-based care models, and limit out-of-pocket costs for patients.

We believe it's not enough to run our business well – we also must operate the right way, with integrity and transparency. Building trust – with our patients and customers, and all our stakeholders – is one of our key corporate priorities, helping us achieve our vision to be the most valued and trusted medicines company in the world. A critical tool in this effort is our Code of Ethics, which was created by



our associates for our associates, to help them make decisions that are aligned with our values and ethical principles. In 2021, we reaffirmed our commitment to patient engagement in the Code of Ethics. This report includes several stories that illustrate some of the many ways we seek out and incorporate patient input.

Looking ahead, we are hopeful about the future of medicine and its role in helping people live longer and better lives. We also know that much still needs to be done to ensure that everyone has full and equal access to the benefits of biomedical advancements. We hope you will join us in working to build a strong, sustainable and equitable healthcare system – and society – that we can all be proud of.

Sincerely,

Novartis US Country Leadership Veam

US Country Leadership Team

(top to bottom, left to right):
Linda Armstrong, MD, Alexandra Bach-Weidmuller, Victor Bultó, Emily Chee,
Tracy Furey, Keren Haruvi, Reshema
Kemps-Polanco, Shefali Kothari,
Patrice Matchaba, MD, Elizabeth McGee,
John McKenna, Courtney Piron, Vicki
Rawlinson, Julie Sanchez, Jonathan
Smith, Mary Treacy

Building a More Diverse, Equitable and Inclusive Healthcare System

Novartis and the Novartis US Foundation have launched Beacon of Hope, a ten-year USD 33.7 million collaboration with 27 historically black colleges, universities and medical schools and other organizations to create actionable solutions targeting the systemic racism that drives inequitable health outcomes in the US. Our initiative commits us to work together with like-minded stakeholders for health equity progress through greater diversity and inclusion across the healthcare ecosystem.

Scope of the challenge

"Of all the forms of inequality, injustice in healthcare is the most shocking and inhumane." These words by Dr. Martin Luther King, Jr. resonate loudly today, as the COVID-19 pandemic and other health challenges continue to cause unnecessary death, disability and suffering across resource-constrained communities, especially communities of color.

In the US, the death rate from COVID-19 among Black and African American people is nearly double that of white people. Hispanic people also suffer higher death rates from the pandemic. Other serious diseases – including heart disease, cancer and diabetes – disproportionately impact minority communities as well.

Disparities are endemic across our healthcare system. Minorities are significantly underrepresented in clinical studies, comprising just 2-16% of participants, and this impedes the development of new treatments. Black and African American people also are woefully underrepresented in US medical schools and across the healthcare field, comprising only 6.2% of medical school graduates, 5% of practicing physicians, and an even smaller percentage of clinical trial investigators.

The causes of these stark disparities are many, but in large part they are directly tied to deeply rooted inequities arising from historic racism and prejudice, poverty and lack of resources, poor understanding of health needs of diverse populations, and lack of trust in the healthcare system. Health inequities in the US based on race are not only unethical, they also cost lives, waste resources and hold society back.



Marion Brooks, Head of US Diversity & Inclusion at Novartis, with David M. Carlisle, MD, PhD, President and CEO of Charles R. Drew University of Medicine and Science

Novartis taking the initiative

For some time, Novartis has been focused on addressing systemic and deep-seated inequities in our healthcare system in the US, through initiatives by our company as well as the Novartis US Foundation. For example, our research and development organization has been putting in place innovative measures to improve racial and gender diversity in our clinical trials. Our US Foundation also has made health equity a centerpiece of its programming.

Building on these achievements in 2021, Novartis took a major step forward to address the root causes of disparities in health and education by launching Beacon of Hope, an innovative ten-year collaboration with 27 Historically Black Colleges and Universities (HBCUs), including HBCU medical schools; the National Medical Association; Thurgood Marshall College Fund; and Coursera. The goal is to co-create effective, measurable solutions for health equity, focusing in four key areas.

First, we plan to enable the next generation of Black and African American leaders by creating equitable access to high quality educational and professional development. In collaboration with Thurgood Marshall College Fund, the Novartis US Foundation plans to invest USD 20 million in scholarships, mentorships, internships and research grants to help prepare up to 1 200 Black and African American students to become the next generation of leaders in health, science, technology and business.



Attracting talent from HBCUs

For the last two years, our cardiovascular, renal and metabolic sales organization has worked with Historically Black Colleges and Universities (HBCUs) to help attract top diverse talent to Novartis. One of these recruits is Genesis Peterson, a graduate of South Carolina State University, who joined the company in 2020 as part of the sales team supporting our cardiovascular therapies. "In my family, I've seen what untreated heart disease looks like," he says. "I've also seen the huge difference innovative medicines can make in the lives of patients and their families and loved ones."

With cardiovascular disease disproportionately affecting Black and other people of color, Genesis understands why it's so important for minorities to be part of the search for new treatments, and also feel they can trust their healthcare provider and system. "Beacon of Hope will build on our company's close relationship with HBCUs to help make our healthcare system more responsive to the needs of Black, African American and other minority patients," he says.



"Our Beacon of Hope initiative is a major step forward to address the root causes of disparities in health and education that cost lives, hurt minority communities and cripple society. Working with stakeholders, we aim to build a more diverse, equitable and inclusive healthcare system benefitting all of us."

Patrice Matchaba, MD, Head, US Corporate Responsibility & President, Novartis US Foundation

Second, the Novartis US Foundation intends to invest approximately USD 13.7 million to establish three digitally enabled research centers at Morehouse School of Medicine, a leading HBCU. This support includes building a clinical trial center of excellence that could be a model for possible expansion to other HBCU medical schools, to increase diversity among clinical trial investigators and participants. This will help us find better treatments for diseases affecting underserved populations and also build greater trust in our healthcare system.

Third, we are initiating efforts to research and validate existing data standards that drive diagnosis, clinical trial endpoints and population health policy, to identify areas for increased inclusivity and ensure accurate data collection and unbiased treatment decisions. There is extensive evidence showing that flawed data and data interpretation have contributed to inequities in the way minorities are diagnosed and treated for certain diseases.

Finally, we are establishing digitally enabled research centers looking at the impact of the environment and climate change on health, to identify solutions to environmental and climate issues that disproportionately affect communities of color.

"Beacon of Hope is modeled on other longstanding global collaborations led by Novartis that are helping to build healthcare capacity and find novel approaches to fighting serious diseases largely affecting disadvantaged populations," says Patrice Matchaba, MD, head, US Corporate Responsibility and president of the Novartis US Foundation. "We are grateful to all our stakeholders who share our commitment to building greater equity in our healthcare system, and especially to the Morehouse School of Medicine, led by its president and CEO, Dr. Valerie Montgomery Rice, which early on recognized the tremendous potential in this transformational initiative and has taken a key leadership role in it."

Corporate Responsibility

We believe that corporate responsibility is about creating shared value with society. Our programs and initiatives in Environmental, Social and Governance (ESG) areas address many of the pressing issues that impact people and communities broadly. Our first Materiality Assessment for the US provides important stakeholder input in key areas, such as diversity and inclusion, health equity and environmental sustainability, where Novartis can take action to drive change.

Building a more diverse and inclusive Novartis

Diversity & Inclusion (D&I) lives at the heart of our culture as an inspired, curious and unbossed organization and is an integral part of everything we do. It is key to driving innovation and business performance as we push boundaries and reimagine medicine to improve and extend people's lives.

We aspire to have an associate population – including, importantly, at the senior levels – that reflects the people we serve. We are actively working to boost opportunities for women and people of color across the organization through initiatives that are yielding results.

For example, beginning in 2020, we implemented guidelines requiring gender and racial/ethnic diversity both in slates of candidates under consideration for open positions and in the panels interviewing candidates. More than 85% of our candidate slates are now diverse relative to gender as well as in their racial/ethnic representation. In addition, Novartis hired a dedicated D&I talent acquisition team to help us identify and attract diverse talent to the company.

We have several internal D&I programs to help develop our people. They include Leading Up, a six-month development program specifically designed for emerging women leaders. Participants engage in a comprehensive exploration

of their career goals, personal development and impact on the organization.

Additionally, our Multicultural Engagement Program is designed to strengthen our inclusion efforts, ensure engagement and improve retention of ethnically and racially diverse associates. In 2021 we expanded the program to include Hispanic associates in addition to African American/ Black associates. Participants are provided executive coaches mentors along with learning sessions to accelerate their personal and professional development. These resources also help them prepare for senior leadership roles in the organization.

2021 D&I Awards and Rankings



DiversityInc Hall of Fame Company



Best Places to Work for LGBTQ Equality

Human Rights Campaign



Refinitiv Diversity & Inclusion Index

First in pharmaceutical category, second year in a row



Bloomberg Gender Equality Index

Recognized for achieving the highest standards in measures of inclusion such as female empowerment and gender pay equity



Forbes Best Employers for Women



Forbes Best Employers for Diversity

LEARN MORE ABOUT US

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

A FULL DISCUSSION OF NOVARTIS D&I PROGRAMS

→ www.novartis.us/sites/ www.novartis.us/files/ nvs-eeo-di-report-2021.pdf



"As Executive Sponsor for PRIDE, one of the many Employee Resource Groups at Novartis, I experience first-hand how important it is for all associates to be given voice at Novartis, one that helps all of us learn and grow. These groups are wellsprings of talent and business acumen, as well as an attractive draw for those considering joining our company."

Tracy Furey, Head, Global Oncology and Americas Communications & Engagement

It is important to have a pharmaceutical sales force that reflects the diverse patients we serve. To this end, we implemented a diversity hiring initiative in our Cardiovascular, Renal and Metabolic (CRM) sales organization to help us better meet the needs of communities of color. Many serious diseases, including heart and kidney disease and diabetes, disproportionately affect minority populations.

CRM hiring managers work directly with recruiters to put together diverse candidate pools and slates across the US, and also liaise with key groups such as alumni from Historically Black Colleges and Universities (HBCUs) to help attract top diverse talent.

In addition to employee engagement and retention initiatives, gender equity is another key part of our commitment to D&I. Novartis continues to make progress toward our Equal Pay International Coalition (EPIC) pledge to achieve gender balance in management and improve pay equity and transparen-

cy processes globally by 2023. To realize these goals, we have implemented a number of equity-focused recruitment, engagement and retention policies that are achieving results. In 2021, the percentage of women in Novartis management in the US was 49%.

To help meet our EPIC pay equity and transparency commitments, we started sharing with our associates their pay as compared to external benchmarks, and plan to expand this to internal benchmarks in 2022.

Addressing health inequities

Our commitment to diversity and inclusion extends beyond the workplace as we strive to build a stronger, more equitable and more inclusive society broadly. Through initiatives led by our company as well as the Novartis US Foundation, we are focused on addressing persistent disparities of care that significantly impact individuals, families and communities of color.

ASSOCIATES MAKING A DIFFERENCE

Novartis associates donate generously to nonprofit organizations that provide important public services, help people in need and strengthen communities. Many of their contributions are matched by the Novartis US Foundation.

USD5MM

2021 associate donations, including USD 2.6 million in matching funds from the Novartis US Foundation

We take a comprehensive approach, focusing on building enduring collaborations with health systems as well as patient and community organizations that share our goals to further health equity. The COVID-19 pandemic has given added urgency to this task, underscoring the high cost health inequities impose on people and societies.

Novartis equity initiatives in critical disease areas

Deaths from cardiovascular disease (CVD) are on the rise again, with worsening outcomes in racial and ethnic minority communities. In response, Novartis collaborated with Thomas

Jefferson University in 2021 to launch Closing the Gap, a three-year initiative to address social determinants of health that contribute to adverse CVD outcomes in underserved neighborhoods of Philadelphia.

The program will provide a range of critical services, including building connections between the community and healthcare system to break down barriers that inhibit access to care; offering community-based health screenings; helping to secure housing assistance, workforce training and food access; educating on CVD risk factors; and offering access to physical and wellness

programs. It also will address policy and structural issues through community capacity building and advocacy.



"Collaborating with others to tackle the drivers of health disparities and designing systems to improve access to quality healthcare are vital to our mission to improve lives."

Sandra E. Brooks, MD, MBA, Executive Vice President and Chief Community Health Equity Officer, Thomas Jefferson University

Breast cancer is another area where disparities of care directly affect health outcomes. Black women with breast cancer are approximately 40% more likely to die compared to white women in the US, and Black women are more likely to be diagnosed at a later stage with a more aggressive disease.

In 2021, Novartis launched More Than Just Words, a multiyear commitment to promote health equity in breast cancer care. As part of this initiative, we are enlisting multidisciplinary experts in breast cancer and health policy to identify the most pressing issues facing Black women with breast cancer, and collaborate to build solutions.



Valuing veteran experience

We know that our commitment to find talent with diverse experiences and backgrounds makes us a stronger and more effective organization. It also helps us meet the needs of the diverse patients and other stakeholders we serve.

One of our unique diversity recruitment initiatives focuses on US military veterans – like Dan Burger. A Ranger-qualified infantry officer in the Army, Dan held combat positions in southern Afghanistan and also was an instructor in infantry school, rising to the rank of captain. The skills he learned in these and other roles on and off the battlefield – leadership, esprit de corps, self-discipline, strategic thinking – have served him well as an institutional sales specialist for the cardiovascular sales force in central Michigan. "I wanted a purposeful career after the Army, and quickly saw that this kind of a sales position – supporting lifesaving heart medicines – fit that bill," he says.



"One of the things that makes Novartis unique is our focus on our inspired, curious and unbossed culture. This means developing inclusive leaders who are able to empower their teams by being open to new ideas, removing obstacles to drive collaboration and performance, and helping others reach their full potential."

Vicki Rawlinson, Head, People and Organization US

For more than a decade, Novartis has been working to better understand sickle cell disease (SCD) – a painful and life-threatening condition that disproportionately affects individuals of African ancestry and other people of color – and find improved treatments for it. In 2021, we announced a unique collaboration with the Bill & Melinda Gates Foundation to discover and develop an accessible in vivo gene therapy for the disease as well as address disparities in access to treatments.

In addition, the Novartis US Foundation has enabled the expansion of the CDC Foundation's Sickle Cell Data Collection Program, which seeks to better understand the epidemiology of the disease in the US, focusing on gaps in diagnosis, treatment and care.

Novartis US Foundation

The Novartis US Foundation is dedicated to confronting health disparities by creating and supporting innovative and sustainable solutions to expand access to healthcare and build trust within the health system. To achieve this goal, the Foundation supports collaborations and programs to increase diversity in the healthcare workforce and address implicit bias in the system; improve

access and remove barriers to healthcare services for vulnerable populations; and provide aid and support to address social determinants of health in local communities.

The US Foundation is playing a central role in the company's Beacon of Hope initiative to boost minority participation in clinical trials, to better understand racial disparities related to data standards and environmental conditions, and to improve educational opportunities for Black and African American students. This builds on the US Foundation's previously announced commitment to understanding and addressing the vast underrepresentation of Black and African Americans, Native Americans, Hispanics and other minorities in clinical trials.

In addition, the US Foundation has worked with several organizations to address systemic issues that are related to health inequities. A pilot program, led by the New Jersey Primary Care Association, enabled five community health centers throughout New Jersey to provide new telehealth services for vulnerable patients. With these additional capabilities, the centers were able to reduce barriers and deliver high quality care to patients.

The US Foundation also collaborated with the Institute for Healthcare Improvement (IHI) to support their equity learning and action network of 22 healthcare organizations. IHI provided technical assistance and other education opportunities to the participants, resulting in increased learning about best practices related to reducing racism within the health system, strategies for addressing vaccine equity and vaccine hesitancy, and tools for measuring the impact of these efforts in their communities.

Environmental sustainability

Our commitment to environmental sustainability is an important part of how we build trust with society. It also aligns with our purpose: unless we can operate sustainably, our work to improve and extend people's lives may be compromised by the environmental impact of our efforts.

In 2021, we adopted a new, four-pillar strategy to accelerate achievement of our mid- and long-term targets to reduce carbon emissions, water usage and waste. Full details of our global strategy on environmental sustainability are included in our global Novartis in Society Integrated Report 2021.

Embed a mindset of sustainability in how we operate

We aim to create a culture in which sustainability is embedded throughout the decision-making process. To this end, in 2021 we established a Green Ambassadors Network to communicate, sponsor and share sustainability initiatives among local and global teams.

A good example of a sustainability mindset in action is a project at our Morris Plains, New Jersey, manufacturing facility to recycle the shoe covers that are required for clean room operations at the site. Since the program was implemented in 2019, it has prevented more than 38 000 pounds of used shoe covers from going to landfills. And by compressing the shoe covers into batches, the facility was able to reduce 26 shipments of discarded shoe covers per year to just one per quarter.

Be carbon neutral, plastic neutral and water sustainable

We are meeting the challenge of shrinking our carbon footprint in multiple ways. We have committed to achieving Net Zero carbon emissions across our value chain by 2040. We are reducing our electricity demand and accelerating our procurement of renewable energy. Our virtual power purchasing agreement with the Santa Rita East windfarm in Texas is

now enabling us to offset all our US emissions using energy attribute certificates.

We are also using a coordinated approach with our suppliers to apply, where possible, the same high standards of environmental sustainability that we hold ourselves to. In 2021, we launched our Novartis Green Expectations from Suppliers initiative, which requires suppliers to map out their emissions, water and waste policies, as well as set goals and report their progress.

In 2021, Novartis received My Green Lab certification, a third-party framework that aims to raise awareness of environmental sustainability in laboratory settings and encourage researchers to reduce waste, energy and water. More than 300 Novartis researchers across 24 laboratory sites in the US and overseas took part in the certification process.

Using smart adjustments in shipping algorithms, we reduced our clinical trial-related medical shipments by more than 40% in 2021, without any negative impact on trial progress or patient care. This avoided more than 36 000 shipments and represents a reduction of approximately 2 800 tons of CO₂ annually.

Our Science Operations team at the Novartis Institutes for BioMedical Re-

search facility in Cambridge, Massachusetts, upgraded its ultra-deep freezer fleet with high efficiency models and retired older models over the last two years. Ultra-deep freezers (minus 80 degrees Celsius) are needed for research work, but are highly energy-intensive. We estimate these changes will result in a reduction of approximately 123 tons of CO₂ annually.

We also are moving forward with our water goals. By 2025, we aim to reduce our water consumption by 50% against our 2016 baseline and have no water quality impacts from manufacturing effluents. By 2030 our goal is to be water neutral, meaning that the amount of water Novartis withdraws from the local environment will not contribute to the depletion of local water reserves.

Develop and deliver more sustainable products to our patients

Novartis is committed to embedding environmental sustainability into the design of our new products, devices and packaging. We assess the environmental impact associated with all stages of a product's life, from raw material extraction to processing, manufacturing, distribution, use and disposal.

Be recognized as a role model, driving and influencing change internationally

We aim to positively influence the global environmental sustainability agenda. In 2021, we became a signatory of RE100, a global initiative of businesses committed to 100% renewable electricity, led by the Climate Group in collaboration with the global environmental reporting nonprofit CDP.

Our associates also launched One Young World – Novartis Caucus 2021 Operation Planetary Health, designed to raise awareness about environmental sustainability and create a movement to accelerate change within the company. The Caucus was an innovation challenge that enabled all associates with an interest in environmental sustainability to come together to support Novartis in making a bold impact on planetary health.

Enhancing environmental sustainability

	Our ambition	Targets 2025			Targets 2030			
Climate	Carbon neutrality	1	Carbon neutral own operations scope 1 and 2	3	Total carbon footprint neutrality scope 1, 2 & 3			
		2	Environmental criteria in all supplier contracts					
Waste	Circular economy & plastic	4	Eliminate PVC in packaging	6	Plastic neutral			
	neutrality	5	Waste disposal reduced by half	7	All new products meet sustainable design principles			
Water	Water sustainability	8	Water consumption reduced by half in our operations	10	Water neutral in all areas			
<u>ل</u> ه		9	No water quality impacts from manufacturing effluents	11	Enhance water quality wherever we operate			

LEARN MORE ABOUT OUR GLOBAL ENVIRONMENTAL SUSTAINABILITY GOALS

Science & Innovation

Bringing innovative treatments to patients is at the core of the Novartis purpose. More than 20 000 research and development (R&D) associates around the world – including 5 250 in the US – work to find new medicines to reduce the burden of disease for patients and societies.

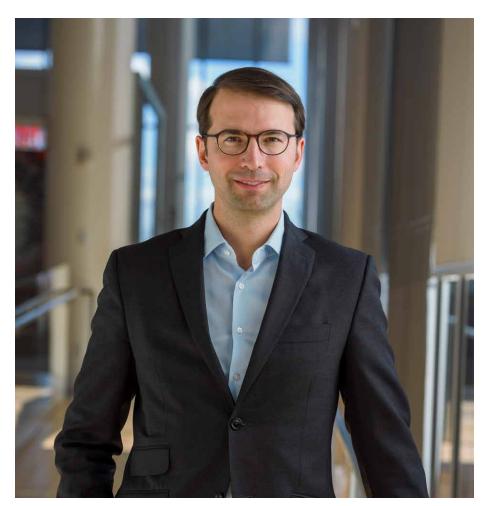
Novartis continued to deliver transformative innovation to patients in 2021. We received 21 major drug approvals in key global markets, including two in the US for important new treatments for high cholesterol and chronic myeloid leukemia. We also made 34 major regulatory submissions. We advanced our diverse pipeline of investigational therapies, with three breakthrough therapy designations from the US Food and

Drug Administration (FDA) and about 20 clinical data readouts paving the way for further launches in 2022 and beyond.

Our R&D efforts span two units. The Novartis Institutes for BioMedical Research (NIBR) leads drug discovery and development from concept to early clinical evaluation, while Global Drug Development (GDD) leads the advanced clinical development of potential new

medicines, running large clinical trials and steering the way to regulatory approval and access for patients.

We prioritize projects with the potential to transform the standard of care for patients. Approximately 85% of our treatments in development have the potential to be first in class or first in a specific indication, while about 80% target areas of high unmet patient need.



"Innovation at Novartis is most visible in the life-changing treatments we bring to people every day. But it's broader than that. Innovation is also how patients access our medicines. It's how we engage with health care providers. It's how we work to bring more agility to our organization to address the complex health challenges of today and tomorrow."

Victor Bultó, Head, Novartis Pharma US & President, Novartis Pharmaceuticals Corporation

2021 approvals and R&D pipeline highlights

Novartis achieved important US and global approvals and advanced our pipeline in cardiovascular disease, cancer, dermatology and other key therapeutic areas in 2021. Building on our success in small molecule therapies and biologics, we are also investing in advanced technologies such as radioligand therapies and gene therapies that offer new treatment paradigms for patients.

The FDA approved *Leqvio* (inclisiran), a novel treatment that reduces low density lipoprotein cholesterol (LDL-C), a highly important modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD). *Leqvio* offers a unique twice-yearly dosing (after an initial dose and another at six months) and a new treatment option for certain ASCVD patients who are unable to reach their LDL-C goal. In addition to the US, *Leqvio* has been approved in more than 50 countries around the world.

In 2021, our heart medicine *Entresto* was granted an expanded indication in the US. It is now approved for the treatment of adult chronic heart failure with left ventricular ejection fraction below normal, allowing for the treatment of most chronic heart failure patients, including many patients with preserved ejection fraction.

In cancer, we received FDA approval in 2021 of *Scemblix* (asciminib) for treatment of chronic myeloid leukemia (CML) in two distinct indications,

offering a new treatment option for patients who are resistant or intolerant to existing therapies. This represents another important milestone in our two-decade-long scientific commitment to patients living with CML.

We are exploring a new, targeted way to treat metastatic castration-resistant prostate cancer (mCRPC) with ¹⁷⁷Lu-PSMA-617, an investigative radioligand therapy. In 2021, the FDA granted ¹⁷⁷Lu-PSMA-617 a Breakthrough Therapy Designation after a Phase III study showed that the treatment plus existing care options significantly improved overall survival and radiographic progression-free survival for people with mCRPC compared to existing care options alone.

We continue to see results from the clinical program for our breast cancer treatment *Kisqali*. The results of a Phase III study announced in 2021 showed that *Kisqali* in combination with an aromatase inhibitor achieved an overall survival benefit of more than five years for postmenopausal women with HR+/HER2- advanced breast cancer. The data represent the longest reported median survival from a randomized trial in HR+/HER2- advanced breast cancer, which is the most common subtype of the disease.

Cosentyx, our treatment for several systemic inflammatory conditions, continues to show strength in addressing a variety of debilitating dermatological and rheumatological conditions in adults, and now in children.

54

Ongoing Phase III programs

~80%

Novartis treatments in development that target areas of high unmet patient need

"I have spent the last 45 years researching and increasing our scientific understanding of breast cancer, so it is incredibly rewarding to see just how far we've come."

Gabriel N. Hortobagyi, MD, FACP, Professor of Medicine, The University of Texas MD Anderson Cancer Center & Kisqali clinical investigator



"Here at Novartis, we're leading the way in finding promising new treatments for cancer, including using cutting-edge cell and gene therapies as well as promising new technologies to fight tumors. As a result, many cancer patients are today living longer and better lives – with many more advancements to come."

Reshema Kemps-Polanco, Executive Vice President, Oncology US

In 2021, Cosentyx was approved in the US for the treatment of moderate-to-severe plaque psoriasis in pediatric patients aged 6 years and older who are candidates for systemic therapy or phototherapy. This is its first approval in a pediatric population.

We are exploring new ways to treat COVID-19, the most urgent public health issue in the world today. These include efforts to discover a novel therapy targeting the main protease – an enzyme essential to viral replication across coronaviruses, including SARS-CoV-2. The goal is to develop a therapy that could treat many or all other forms of coronaviruses, potentially preventing future pandemics.

We also are collaborating with Molecular Partners to develop MP0420 (ensovibep), which targets the virus using proprietary DARPin^{®1} technology to neutralize SARS-CoV-2. The multi-specific binding modality of DARPin therapeutics has unique advantages for addressing pandemics, including COVID-19, such as a potentially low likelihood of inducing drug resistance.

COVID-19 has led to an increased demand from patients and governments for key generics from our Sandoz Division, including antibiotics and anti-virals, injectables, and other critical medicines. Throughout the pandemic, Sandoz has relentlessly tracked orders and trends to anticipate demand, enacted allocation processes to manage demand, and adapted manufacturing. We also endeavor to hold sufficient safety stock to keep our distributor and wholesaler customers supplied based on agreed-to replenishment lead times.

Advanced therapy platforms

Novartis is investing in new technologies and platforms that offer more targeted approaches to fighting – and, in some cases, potentially curing – serious diseases. We have the depth and scale to discover, develop and commercialize therapies using these advanced platforms.

Radioligand therapy delivers precision-targeted radiation to cancer cells widely disseminated in the body, with the goal of limiting damage to surrounding tissue. It has the potential to address a wide range of cancers and become a major pillar of cancer care.

Novartis has built a strong foundation in this area with *Lutathera*, our first approved radioligand therapy, and with ¹⁷⁷Lu-PSMA-617, our investigational

¹ Registered trademark of Molecular Partners AG

therapy for prostate cancer. Altogether we have more than 15 research and clinical programs underway to identify and accelerate the next generation of radioligand therapies for cancer.

In **gene therapy**, one of our technologies uses benign viruses called adeno-associated viruses (AAVs) to deliver genes to cells inside the body. The goal is to repair the cells with a one-time treatment. Our first approved AAV-based therapy was *Zolgensma*, for spinal muscular atrophy, and we are now exploring experimental forms of gene therapy for other diseases, from brain disease to blood disorders. Altogether we have more than 20 research programs in gene therapy.

With **cell therapy**, a patient has key cell types extracted and genetically modified in a clinical lab before being injected back into the body. An example of this is chimeric antigen receptor T-cell (CAR-T) therapy, a treatment generated from a patient's own T-cells. Novartis was the first pharmaceutical company to significantly invest in pioneering CAR-T research and initiate global CAR-T trials. Our flagship CAR-T therapy, *Kymriah*, was the first cell therapy approved in the US for certain kinds of leukemia and lymphoma.

Novartis has a resilient global CAR-T manufacturing footprint, spanning seven facilities (including one in the US) across four continents. In 2021, we announced the development of a novel manufacturing platform – called T-Charge™ – that is expected to improve the therapeutic potency of the T-cell product while halving the time needed to take cells from the patient, manufacture the product, and return it to a healthcare professional for administration.



When innovation is personal

When you have a chronic, painful disease nearly all your life, you grab on to any hope that new treatments will bring relief. Danielle J. knows all about this as a patient with sickle cell disease (SCD), a condition she has battled since she was three months old. Between 90 000 and 100 000 Americans – mostly individuals of African ancestry and other people of color – are diagnosed with the painful and debilitating disease, which is the most common inherited blood disorder in the US.

For many years Danielle was on a standard treatment for SCD, which did a satisfactory job of managing her condition. Still, she endured recurring pain crises that forced her to go to the hospital every 2-3 months. "Those hospitalizations were terrible, and they really affected my quality of life," she says. A few years ago, her hematologist told her about a clinical trial for a new Novartis SCD medicine, and she signed up. "For most people, innovation is just a buzz word, but for me it means something very personal," she says. "Sickle cell patients know that novel medicines for their condition can give them new opportunities to live their lives and not fear for the future."

Based on her own experience, Danielle is passionate about urging patients to enroll in clinical trials, noting that people of color are significantly underrepresented in medical studies – including those that potentially could benefit them. It's a big part of her advocacy work on behalf of patients and caregivers. "I'm hopeful when I see how much progress is being made in research and development, but also in patient care, education and outreach that are critical to fighting the disease," she says.

Data science and digital technology

We use data and digital strategies across our R&D operations to open new paths to scientific discovery, improve patient outcomes and streamline the development process. Harnessing the power of data science and digital technology is a core part of our ambition to reimagine medicine.

One example is the use of digital devices, such as wearable sensors, to capture continuous data on physical activity, sleep quality or fatigue, which could be used as endpoints in trials for diseases including chronic obstructive pulmonary disease and Sjögren's syndrome. Such "digital endpoints" can improve the relevance and objectivity of clinical trial data, as well as offer new insights.

Digital technology can also make clinical trials more convenient for patients and caregivers by reducing the need for repeated in-person clinical visits. For example, in a Phase III study of our gene therapy *Zolgensma* in older children with spinal muscular atrophy, parents can upload videos of their child's progress remotely from home.

Our investments in digital technology helped to keep our clinical trials on track during the COVID-19 pandemic. For example, more than 15 000 potential trial participants in the US used an online enrollment portal, which resulted in referrals of 1500 patients to ten trials. In one Phase II trial, digital recruitment contributed over 25% of the cohort of randomized patients.

We used another digital tool to forecast COVID-19 case progression and anticipate disruptions to clinical trials. For example, in one trial we identified potential delays of up to several months in patient enrollment and first visits related to specific locations. By redirecting resources to compensate, we reduced this gap to a few weeks. In other trials, we switched to remote solutions such as home nursing and home delivery of the investigational product.

Diversity and inclusion in clinical trials

We strive to include diverse patient populations in our clinical trials, both to understand how patients who are most likely to be treated for a disease will respond to a medicine, and because it is the right thing to do.

We are working to address barriers to clinical trial participation, such as identifying sites where patients with a particular disease or condition may be located, identifying healthcare providers who treat underserved or underrepresented populations, and collaborating with researchers to enroll diverse populations in clinical trials.

In 2021, we published our Commitment to Diversity in Clinical Trials. In the short term, we committed to evaluate diversity and inclusion principles for all our Phase III studies with US country participation. In the longer term, we aim to expand this to all our global trials while leveraging data science and digital technology to track diversity data across our drug development programs.

In the US, health disparities affecting minority groups are endemic - an issue that has been highlighted and exacerbated by the COVID-19 pandemic. Compared with non-Hispanic whites, Black and African American communities have a lower life expectancy, higher mortality rates from cancer, greater likelihood of chronic diseases such as asthma, and significantly increased rates of maternal and infant mortality. A major reason for this is lack of access to health providers and resources. Black and African Americans are also proportionally underrepresented in medical schools and among physicians and clinical trial investigators.

In 2021, Novartis and the Novartis US Foundation announced plans to invest approximately USD 13.7 million to establish three research centers at Morehouse School of Medicine in Georgia, including a clinical trial center of excellence that could be a model for possible expansion to other Historically Black Colleges and Universities (HBCUs).

The investment is part of a 10-year commitment with 27 HBCUs and other organizations. The objective is to co-create programs that address the root causes of systemic disparities in health outcomes and foster greater diversity, equity and inclusion across the research and development ecosystem.





Value & Access

Novartis believes that medicines should be priced according to the value they deliver to patients, to our healthcare system and to society. We also believe that patients should have access to quality medicines and healthcare, regardless of their financial situation. Through our efforts with policymakers, payors, and patient organizations, we are taking a leading role in advocating for innovative value-based approaches to expand access to medicines and strengthen our healthcare system.

Value-based pricing

Pharmaceutical pricing remains a prominent focus in the US. The rise in chronic diseases, along with the aging population, are driving an increase in demand for healthcare and causing payors to take steps to contain spending growth.

At Novartis, we want to be a part of the solution to this challenge. We aim to price our medicines according to the value they deliver to patients, health-care systems and society. We believe this approach incentivizes healthcare systems to focus on interventions that deliver the most effective, efficient and sustainable outcomes.

We consider the following elements in proposing the price of our innovative medicines:

- Do our medicines help to increase patient quality of life and/or patient safety?
- Do our medicines help to increase efficiency in the healthcare system and/or reduce costs elsewhere in the system, for example by preventing hospitalizations?
- Do our medicines have a societal impact beyond the immediate healthcare benefit, such as helping to improve economic productivity or address health disparities?

A good example of this approach is our heart medicine *Entresto*. Value criteria, such as clinical and patient outcomes – along with cost offsets from reduced hospitalizations – have played a role in the way Novartis has priced *Entresto*.

A variety of approaches exist on how to measure the value of our medicines. We aim to generate transparent, real-world evidence to support the most accurate possible value assessment for our medicines. We stand ready to support and strengthen our healthcare system in the journey towards value-based care, so the price of medicines overall can more closely and consistently align with our access principles.



Going the extra mile for patients

Starting a new medicine can be intimidating – especially if it requires a self-administered injection. Carol Welch knows all about this as a Novartis Patient Services Coordinator (PSC) for *Kesimpta*, our treatment of adults with relapsing forms of multiple sclerosis (MS). "My job is to engage with patients on *Kesimpta* and empower them through education and advocacy," she says.

When *Kesimpta* was approved in the US in 2020, Novartis also set up the Alongside Kesimpta program to support patients for their first two years on therapy. PSCs interact one-on-one with patients, providing education on MS and *Kesimpta* along with virtual injection demonstrations. This service is free of charge and open to all patients on *Kesimpta*, either through physician referral or direct patient enrollment on www.kesimpta.com.

Alongside participants value the fact that one coordinator is assigned to them for the duration of their time in the program. "I reach out with calls, emails and texts – however the patient likes to communicate with me," Carol says. In addition to providing very practical information, she gives ongoing support to patients. "I cheer them on for their successes and follow up on special events like their birthday."

Carol loves her job and the ability to provide this kind of personalized service. "It makes me feel good that the company I'm part of is committed to go the extra mile to support our patients," she says.

US Pricing

Across our branded products, we limit our aggregate portfolio net price increases to at or below the National Healthcare Expenditures rate as determined by the US Centers for Medicare and Medicaid Services.

In 2021, political debates at the federal and state levels intensified over proposed drug pricing reforms. Novartis supports legislation to reform Medicare Part D to cap out-of-pocket costs at USD 2 000 per year as a way to reduce the cost burden on seniors.

Advocating for patient access and affordability

Novartis engages regularly with policymakers to find sustainable solutions to advance patient health and improve care. Specifically, we want to increase opportunities for patients to access medicines, reduce 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.

For example, we have been working with patient advocates and healthcare providers to urge state health authorities to add spinal muscular atrophy (SMA) to the list of diseases that are recommended for newborn screening. Screening makes it possible for infants diagnosed with SMA to be treated early for this devastating disease. As of the end of 2021, 85% of newborns are being screened for SMA in 38 states.

In 2021, we worked with the sickle cell disease (SCD) community in Michigan to secure USD 6.7 million in the state budget to cover the cost of SCD treatment for approximately 400 adults as well as increased outreach and clinical capacity for the estimated 4000 Michigan residents living with the disease. This builds on our

efforts in California, where we secured USD 15 million for seven clinics to treat adults with SCD.

Co-pay cards offered by Novartis and other pharmaceutical companies help thousands of eligible patients afford their medicines. We support federal and state legislation that limits a health plan's ability to restrict the use of copay cards. Currently, 12 states and Puerto Rico have passed legislation to ensure patients' copay assistance can count toward their deductible, and we are working to expand this protection to other states.

In addition, we are calling for reforms to allow patients to benefit from rebates, which currently go directly from pharmaceutical companies to pharmacy benefit managers on behalf of health plans. We strongly advocate for federal and state legislation that would limit annual patient out-of-pocket costs for their medicines, which could significantly improve access.

Patient engagement and access programs

Novartis engages with patients in a number of ways to help them access their medicines and understand their healthcare. For example, we can help guide patients through the process of seeking insurance reimbursement for their treatments. And we offer education, training and outreach programs tailored to the needs of patients and caregivers.

We recognize that some patients find it difficult to afford their medicines. The Novartis Patient Assistance Foundation (NPAF) provides Novartis treatments at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage.



After joining the Novartis Covered Until You're Covered program, Nadia E. was able to start her *Cosentyx* therapy without delay and at no cost to her while her insurance coverage was being pursued.

In 2021, NPAF provided more than USD 4 billion in free medicines to more than 127 000 patients, covering 71 medicines from our portfolio. Over the last five years, medication valued at USD 13.5 billion has been made available to 445 000 patients.

NPAF adapted quickly to the challenges of the COVID-19 pandemic, implementing measures to ensure that patients continued to receive their medicines on time and reduce additional paperwork burden on patients and healthcare providers. NPAF also modified processes for gathering and reviewing documentation, expanded timeframes for prescription renewals, and shipped patients a longer supply of medicines.

Novartis has a co-pay assistance program in the US that helps thousands of patients with commercial insurance access our medicines at reduced cost to them. Most patients in the program 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.

Responsible Business Practices

Acting in an ethical manner is essential to building trust with society. Our patients and other stakeholders expect us not only to do what is legally required, but also to follow high standards of ethical behavior wherever we operate.

Novartis Code of Ethics

Our Code of Ethics helps us ensure that what we do is right for our patients, colleagues, stakeholders and company, as well as for society. It guides our associates to make decisions that are aligned with our values and our ethical principles. And it encourages candid and open dialogue around the challenges we face in our day-to-day responsibilities to reimagine medicine.

We continue to embed our Code of Ethics across the organization. In 2021, 93% of our associates, including 99% in the US, completed training on the Code of Ethics. Further, we took steps to integrate an ethics dialogue into the process for recruiting potential new hires. We also launched a guide for interviewers to assess the ethical profile of senior job candidates and their alignment with the Novartis Values & Behaviors and our Code of Ethics. This will help us ensure that we hire high-integrity leaders who are a good fit for our ethical culture.

Patients are at the center of everything we do at Novartis. In 2021, we reaffirmed

our commitment to patient engagement in the Code of Ethics, to underscore the high priority we place on the input of patients so we can develop innovative treatments faster and create broader access to medicines.

Advocating for patients

As a healthcare company, we are committed to engaging with policymakers as we seek sustainable solutions to advance patient health and improve care. In fact, the vast majority of our interactions with government officials relate to access to and affordability of medical treatments, as well as efforts to strengthen our healthcare system.

For more information on our work in this area, see the Advocating for patient access and affordability section of this report.

Lobbying reporting

Federal and state laws dictate what falls under lobbying in terms of expenditures, reporting and registration. The intent of these laws is to provide transparency and accountability regarding persons who appear before the federal and state governments advocating for policies that would impact their constituencies.

Included in the amount disclosed at the federal level are labor hours of Novartis associates who engage in federal 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.

FIND OUT MORE

- → www.fec.gov/data
- → clerk.house.gov/public_disc/index.aspx
- → soprweb.senate.gov/index. cfm?event=selectfields





"Having a strong ethical framework is critical for Novartis, since trust is at the core of our relationships with patients and other stakeholders. Our Code of Ethics – created by our associates, for our associates – helps us to do what's right for each other and for all the people we serve."

Shefali Kothari, US Country Head, Ethics, Risk and Compliance

Financial political contributions

Novartis engages with US political leaders on issues of importance to our industry, such as patient access and intellectual property. We make political contributions at the federal level and also at the state level where use of corporate and political action committee funds is permissible by state law and otherwise considered appropriate.

In 2021, Novartis made political contributions totaling USD 1 046 442 in the US. This figure includes:

- Contributions to state-oriented political groups, as permitted by state law (USD 325 000)¹
- 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 USD 497 669)² 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 198 773)³.

The Novartis PAC only uses funds received from eligible 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 US 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 US Senate's Office of the Secretary.

- 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 2021, 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, 2021 Federal Election Commission report.

2021 At A Glance

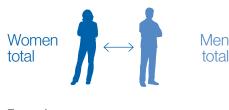
US Equal Employment Opportunity data¹

GENDER

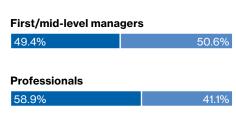
RACE/ETHNICITY

Gender of Novartis US employees by job category

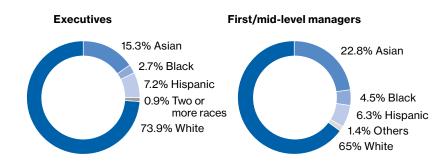
Race or ethnicity of Novartis US employees by job category

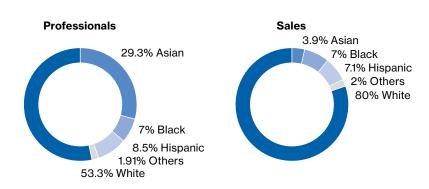












US EQUAL EMPLOYMENT OPPORTUNITY COMMISSION JOB CATEGORIES



Others includes associates who are Native American or Alaskan, Native Hawaiian or other Pacific Islander, or two or more races

Executive/senior-level officials and managers are defined as VPs and above.

First/mid-level officials and managers are defined as all non-executive functional or people managers and supervisors.

Professionals

are defined as non-managers whose roles typically require a bachelor's degree or equivalent – both exempt and non-exempt – excluding sales roles.

Sales workers

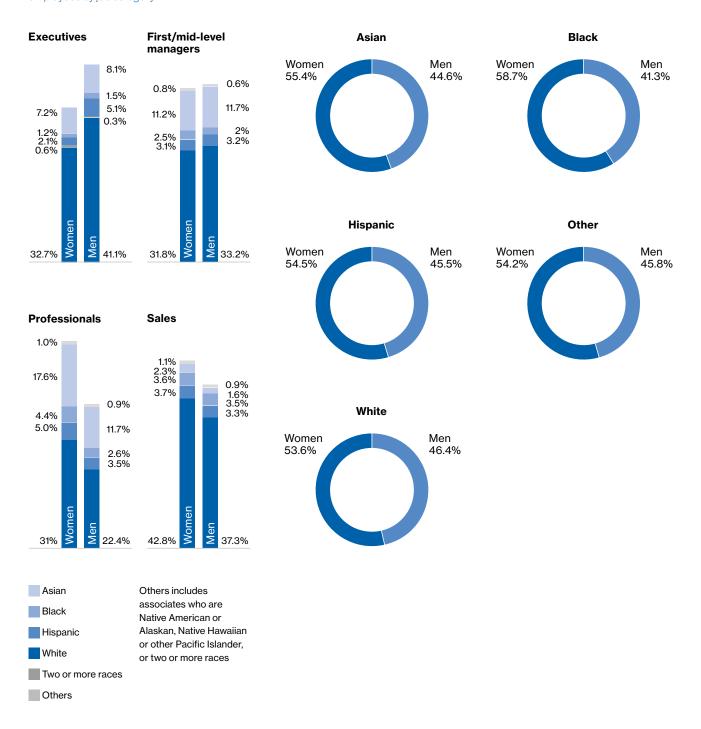
are defined as all non-management sales positions.

¹ From Novartis EEO-1 data as of December 31, 2021

GENDER BY RACE/ETHNICITY

Race, ethnicity and gender of Novartis US employees by job category

Gender of all Novartis US employees by race and ethnicity – not divided by job category



US Product Portfolio

US Product Portfolio¹ - % change vs prior year²

	2017	2018	2019	2020	2021	5 year average
Total gross price change ³	5.4%	5.6%	4.9%	3.7%	3.9%	4.7%
Total net price change ⁴	-2.1%	-1.1%	2.9%	-0.2%	4.2%	0.7%

- US product portfolio for 2017 to 2021 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.

	2017	2018	2019	2020	2021
Total US rebates and discounts ^{1,2}	-49.5%	-49.8%	-48.4%	-46.8%	-45.2%

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 percentages were subjected to agreed upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400.



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 108 000 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 15 000 full-time equivalent employees in skilled positions. For more information, please visit www.novartis.us.

VIEW THE NOVARTIS IN SOCIETY INTEGRATED REPORT 2021:

→ novartis.com/sites/ novartis_com/files/ novartis-integratedreport-2021.pdf

