



Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders



Edition no.18

Q2 2024 Impact and Sustainability Update to investors

Dear investors and analysts,

In our Q2 update, we highlight our approach to addressing the intersection of climate change and human health. We are dedicated to tackling the broader health implications of climate change while remaining committed to our efforts to reduce our own carbon footprint. In line with this, we are pleased to announce that the Science Based Targets initiative (SBTi) has validated our 2040 net-zero target.

In addition, following EU adoption of the Corporate Sustainability Due Diligence Directive (CSDDD) in May 2024, we share our approach to human rights across our operations and chain of activities. As always, we've also included top questions from shareholders in Q2 and our responses.

To foster continued dialogue, we invite you to join our Impact & Sustainability virtual investor event on December 9, 2024. You will receive a separate invitation with a webcast link (which will also be available on our website) in the coming months.

We thank you for your engagement.

For any questions and comments, please reach out to:

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Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Intersection of climate change and human health

Climate change impacts human health

Climate change poses a significant threat to human health, with the potential to undo decades of progress in access to medicines and healthcare system stability. According to a World Economic Forum report, it is estimated that by 2050, climate change will result in an additional 14.5m deaths and USD 12.5tn in economic losses¹.

Factors such as rising temperatures, extreme weather events, biodiversity loss and poor air quality contribute to the broader emergence and spread of both infectious and non-communicable diseases. This impact is particularly pronounced in low- and middle-income countries (LMICs).



Novartis response to climate change: Mitigate and adapt

Novartis takes a multi-pronged approach to address the challenges of climate change. We strive to mitigate our carbon footprint as far as possible and have committed to achieve net-zero greenhouse gas emission across our value chain by 2040, among other → **environmental sustainability efforts**. In 2023, we reduced our emissions (Scope 1 and 2) by 19% vs. prior year (PY) and by 63% vs. 2016 baseline, mainly through energy efficiency, increased use of renewables and new manufacturing technologies. In 2023, our Scope 3 emissions decreased by 3.4% vs. PY.

In addition, we aim to create a global healthcare ecosystem that anticipates and **adapts to climate-driven challenges**, ensuring life-saving treatments reach those in need, regardless of changing global conditions.

Our efforts are focused in three areas:

01 Developing new treatments for diseases likely to spread in changing climates

02 Improving access to medicines in vulnerable regions

03 Strengthening local health care systems

1. World Economic Forum. (2023). Quantifying the Impact of Climate Change on Human Health [Report]. Retrieved March 11, 2024, from <https://www.weforum.org/publications/quantifying-the-impact-of-climate-change-on-human-health/>.

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

01. Developing new treatments for diseases likely to spread in changing climates

Initiative	Activity	Outcome/potential impact
Kigali declaration	Commitment to invest USD 250m over a five-year period (from 2022) into researching and developing medicines for malaria and neglected tropical diseases (NTDs).	Novartis has one of the most extensive pipelines in Global Health with 6 new chemical entities currently in human trials across five disease areas. See positive CALINA study results in malaria → here . By tackling NTDs we aim to foster greater health equity, strengthen health systems, and build resilient communities. The WHO reports that 1.6bn people globally require interventions against NTDs ² .

02. Improving access to medicines in vulnerable regions

Initiative	Activity	Outcome/potential impact
Global health programs in LMICs	Combining global health and business capabilities to tackle unresolved global health challenges such as malaria, sickle cell disease, Chagas disease and leprosy . For example, since 2000, we have delivered >1bn treatment courses of our antimalarial, including >470m courses of our child-friendly formulation in more than 70 countries, contributing to a significant reduction in malaria deaths. The Novartis malaria program is one of the largest access-to-medicine programs in the healthcare industry.	Reached 28.7m patients through our global health flagship programs in 2023.
Novartis Access Principles	Commitment to embed R&D, affordability and health systems strengthening considerations into all commercial activities across value chain. In line with our Access Principles, we price our medicines based on the value they deliver. We use innovative access and pricing models , considering local income levels, affordability barriers and economic realities. Where feasible, we use tiered pricing in LMICs to drive access to our innovative medicines.	100% of new medicines launched with global access strategy since 2021.

2. Reported number of people requiring interventions against Neglected Tropical Diseases (NTDs). Retrieved July 2024 from <https://data.who.int/indicators/i/95935F3/2D6FBE4>.

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Initiative	Activity	Outcome/potential impact
Emerging market brands (EMB)	We continue to expand our EMB program introduced in 2014 to improve access to innovative medicines in LMICs in a way that is sustainable for the business.	In 2023, EMBs reached a total of 792k patients , with the Entresto® EMB reaching 656k patients in LMICs, in addition to patients reached through the original brand.

03. Strengthening local healthcare systems

Initiative	Activity	Outcome/potential impact
Cùng Sống Khỏe (CSK) in Vietnam	Partnering with the government to strengthen the primary healthcare system to deliver hypertension and diabetes care. The program is piloting dyslipidemia testing in primary care, and compiling learnings on the atherosclerotic cardiovascular disease patient journey.	As of 2023, reached close to 2m people across 37 provinces in Vietnam since program inception. World Bank has committed USD 10m to expand the program to include testing and treatment for dyslipidemia.
CVD Rwanda Model	Partnering with the Rwanda Ministry of Health to tackle cardiovascular diseases (CVD), including implementation of an integrated population health approach leveraging data, and delivery of healthcare services including diagnosis.	In Rwanda, CVD poses a public health challenge, with ~10% of all deaths attributable to CVD ³ . The program aims to expand access to CV medicines; improve diagnosis, treatment and care; and improve patient outcomes.

3. World Health Organization. (2023). Rwanda: NCD mortality and morbidity. Retrieved from WHO. Ntirenganya, J. B., & Ntakiyiruta, G. (2021). Perceived cardiovascular disease risk and tailored communication strategies among rural and urban community dwellers in Rwanda: A qualitative study. BMC Public Health. Retrieved from BioMed Central.

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Unmet need

Significant progress has been made against malaria in recent decades. Novartis has played a significant role in these efforts, delivering over one billion treatments of our artemisinin-based combination therapy (ACT) Coartem® to endemic countries since 1999, including a pediatric formulation. However, there is currently no evidence-based treatment for the smallest babies with malaria. **Infants below 5kg make up a critical neglected group**, and developing an antimalarial specifically suited to their needs is an important step towards ensuring all patients can access an appropriate treatment.

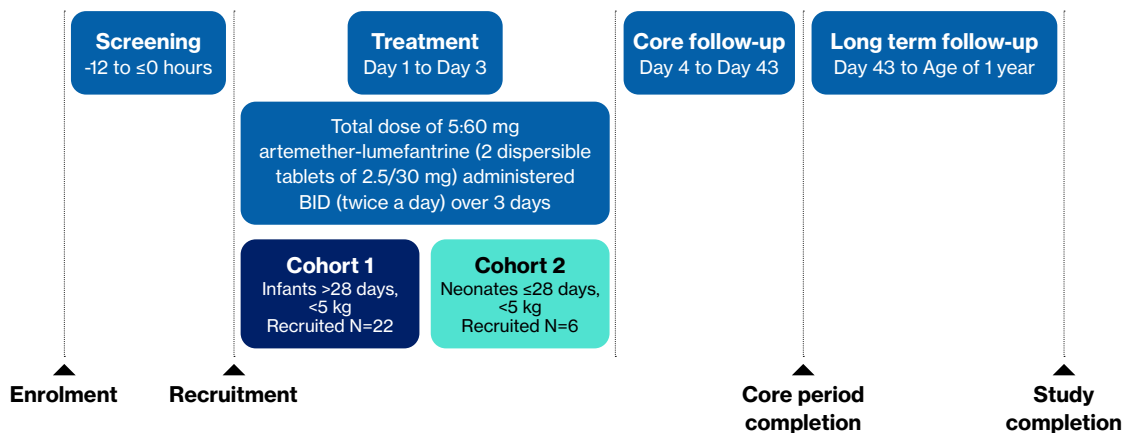
CALINA study

Novartis conducted the **first evidence-based trial** to evaluate an optimized Coartem® dose and regimen for infants weighing under 5kg with acute uncomplicated malaria.

Study design

CALINA enrolled infants and neonates <5 kg

The CALINA study, an open-label, single-arm study, was conducted in patients with acute uncomplicated malaria with body weight <5 kg.



The trial evaluated the pharmacokinetics (PK), safety, tolerability and efficacy of a new dose regimen, with a specific focus on one of the ingredient levels (artemether), which had previously been shown to be high when babies <5kg were administered normal Coartem® dispersible tablets. Patients were recruited in Burkina Faso and the Democratic Republic of the Congo.

Conclusions

The study **met its primary PK endpoint** for patients >28 days of age. For patients ≤28 days of age, the sample size was too small for a conclusive statistical evaluation; however, the PK parameters fell within the required efficacy and safety range. This indicates that the new dose regimen/formulation is an appropriate treatment for infants below 5kg, addressing a key unmet need.



Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

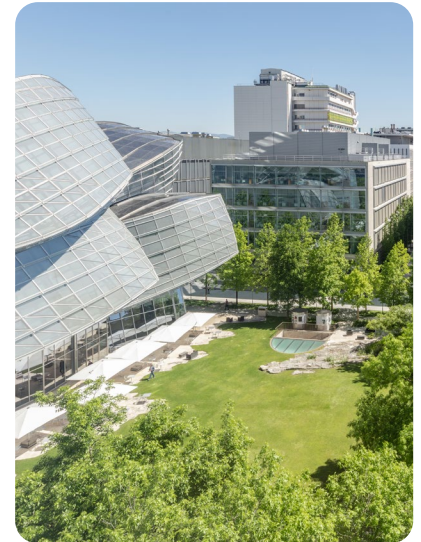
Novartis climate targets validated by SBTi

In July 2024, the Science Based Targets initiative (SBTi)⁴ approved Novartis near- and long-term science-based emissions reduction targets, marking the next milestone in our decarbonization journey.

SBTi has determined that Novartis scope 1 and 2 near-term target ambition is in line with a 1.5°C trajectory, and that Novartis scope 1, 2, and 3 long-term target ambitions are aligned with the SBTi's 1.5°C mitigation pathways for reaching net-zero by 2050 or sooner. SBTi also commended Novartis for its ambitious net-zero target, currently the most ambitious designation available through the SBTi process.

Overview of Novartis climate targets

- ▶ **2025 target**
Become carbon neutral in our own operations (Scope 1 and 2 from energy) from a 2016 base year.
- ▶ **2030 near-term science-based targets (SBTi approved)**
Reduce absolute scope 1 and 2 greenhouse gas (GHG) emissions by 90% from a 2022 base year. Novartis also committed to reduce absolute scope 3 GHG emissions 42% within the same timeframe.
- ▶ **2040 net-zero science-based targets (SBTi approved)**
Maintain a minimum of 90% absolute scope 1 and 2 emissions reductions from 2030 through 2040 from a 2022 base year. Novartis further committed to reduce absolute scope 3 greenhouse gas emissions by 90% from a 2022 base year.



The validation of our near- and long-term emissions reduction targets by SBTi, an independent organization, helps ensure that our emissions reduction goals align with the latest climate science.



4. The Science Based Targets initiative (SBTi), a collaboration between leading organizations like CDP (the former Climate Disclosure Project), the United Nations Global Compact, the World Resources Institute (WRI), and the World Wide Fund for Nature (WWF), supports companies establish scientifically backed greenhouse gas reduction targets. It is focused on accelerating companies across the world to halve emissions before 2030 and achieve net-zero emissions before 2050.

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EU CSDDD

Top 10 questions from shareholders

Novartis approach to human rights and the EU CSDDD

The Corporate Sustainability Due Diligence Directive (CSDDD)

In May 2024, the EU adopted the CSDDD, which requires companies to conduct human rights and environmental due diligence across their own operations and “chain of activities”⁵. The Directive will be transposed into EU member national law over the next two years and compliance will be required by 2027. Novartis is in scope of the Directive. This update provides an overview of our approach to human rights.

Our approach to human rights

Novartis formalized its management of human rights in 2017, aligned with the voluntary UN Guiding Principles on Business and Human Rights. Our approach is reflected in our latest → [Human Rights Commitment Statement](#).

As human rights is part of our integrated assurance approach at Novartis, we leverage our integrated governance, risk management, compliance and control framework for the implementation of our human rights commitment statement. We also collaborate closely with our industry and cross-industry peers to identify risks and engage with stakeholders, all broadly aligned with the CSDDD requirements. For example, we actively participate in PSCI⁶ and Healthcare and Human Rights Forum and engage with the Business & Human Rights Resource Centre.




Preparing to comply with the CSDDD


We have taken a proactive approach to building a human rights management program over the last 6 years. The CSDDD has five core requirements; our key efforts in these areas are outlined below.

CSDDD core requirement

Novartis efforts and select examples

 **Policies**
Adopt and embed human rights & environmental due diligence into relevant policies

- Published Human Rights Commitment Statement with ongoing review and updates
- → **Health, safety, environmental policy** and → **Third party code** includes environmental commitments with regular review

 **Assessments**
Identify, assess, and prioritize risks and impacts across own operations and “chain of activity”⁵

- Conducted >50 human rights assessments across our value chain since 2017

5. Chain of activities defined as: Upstream – from business partners to raw material sourcing; Downstream – limited to distribution, transport, storage. 6. Pharmaceutical Supply Chain Initiative.



Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EU CSDDD

Top 10 questions from shareholders

CSDDD core requirement



Mitigation

Prevent and mitigate potential impacts, and provide remedy for actual negative impacts; establish adequate grievance mechanism

Novartis efforts and select examples

Our assessments have led to new mitigation measures in:

- Management of high-risk supply chains beyond tier 1
- Direct engagement with workers in our supply chain
- Adopted a new standalone → **Non-Retaliation Policy**



Engagement

Embedding stakeholder engagement throughout due diligence processes

- Working to ensure that stakeholder engagement with those potentially affected by our operations is embedded throughout our process
- Began a program to engage workers directly in supply chains with heightened human rights risk



Monitor & report

Monitor the effectiveness of due diligence; report annually on website

- Publicly report our progress through our Human Rights webpage and various legally mandated reports, e.g. → **Report on child labor due diligence in our supply chain**

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Top 10 impact and sustainability related questions from shareholders and our responses

Access and social impact

Question

Response

01

Can you summarize your access efforts in LMICs and US?

- One quarter of the world's population (2bn people) has no access to basic medicines.
- Our approach to access has evolved over the last two decades from donations towards more sustainable access solutions. We have implemented the Novartis Access Principles, which look at three success factors to drive positive social impact in LMICs:
 1. R&D: Considering access earlier in the drug development cycle.
 2. Affordability: Utilizing emerging market brands and tiered pricing.
 3. Healthcare systems: Partnering to establish the basic foundations of disease management and build up healthcare capabilities.
- We measure our success in implementing the Access Principles against three key targets:
 - +200% 'patients reached' with our innovative therapies in LMICs by 2025.
 - +50% 'patients reached' with global health flagship programs (including malaria, leprosy, sickle cell disease, Chagas disease) in LMICs by 2025 (vs. 2019).
 - 100% new medicines launched have a global access strategy.
- In the US, our efforts focus on addressing social determinants of health, and increasing diversity, trust and inclusion across the R&D ecosystem. For example, we established clinical trial Centers of Excellence at four Historically Black Medical Schools to increase diversity among clinical trial investigators and participants (more details on → [Beacon of Hope initiative](#)).

02

How do you price advanced therapies such as Zolgensma® in LMICs?

- We aim to create sustainable access to Zolgensma® for all patients in need around the world. We believe innovative treatments like Zolgensma® require innovative access approaches, and we seek sustainable solutions that recognize the value of Zolgensma® and achieve appropriate/shared contributions from governments, society and Novartis.
- A value-based approach to healthcare incentivizes the healthcare sector to focus on the interventions that deliver the most effective, efficient and sustainable outcomes. Novartis was among the first pharmaceutical companies to enter into value-based contracting for medicines, linking pricing and reimbursement rates to specific outcomes. Value-based pricing principles consider three elements when proposing the price of innovative medicines:
 1. Patient value, e.g. improvement in motor milestones in the case of Zolgensma®.
 2. Healthcare system value, e.g. one-time therapies with long-term benefit vs. life-long chronic therapies.
 3. Societal value, e.g. increased workforce participation for the patient and caregivers.



Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Question

Response

02

How do you price advanced therapies such as Zolgensma® in LMICs?

- We also offer access options that include deferred payments and pay-over-time options as well as outcomes-based agreements.
- Zolgensma® has reached patients in LMICs including Chile, Mexico, Tunisia, Belarus, India, Malaysia and Vietnam. We have ongoing discussions in several other markets demonstrating our commitment to delivering impact for patients all over the world.

03

What activities are you undertaking to advocate for healthcare access improvements with governmental bodies and industry associations?

- We work with policymakers, governments and industry associations to raise awareness about unmet needs in global health, advocate for coordinated solutions between public & private sectors, and build effective partnerships to improve access to innovative medicines. Examples include:
 - Novartis was the first company to sign up for the Access to Oncology Medicines Coalition (ATOM), and the first to offer an innovative, on-patent medicine. In 2022, we granted a “freedom to operate license” for one of our blood cancer medicines, nilotinib, to the Medicines Patent Pool (MPP) as part of the coalition.
 - In response to a call for a renewed commitment to tackling the rising toll of sickle cell disease (SCD) from African health ministers and the WHO Africa Regional Office, Novartis joined forces with leaders in SCD to launch the World Coalition on SCD. Through the coalition, we aim to decrease childhood mortality and improve the quality of life associated with SCD in LMICs.

04

How do you measure the impact of your medicines in LMICs?

- To date we have been using ‘patients reached’ as a proxy for impact in LMICs.
- However, we recognize that new measurement methods are needed in order to better report on our efforts and plan for future activities. For a number of years, we have been piloting methodologies that correlate health benefits (such as QALYs and DALYs) with socio-economic metrics (such as GDP contribution).
- We are actively working with cross-industry consortia, such as the Value Balancing Alliance, to help standardize impact measurement across the industry.

05

What are your expectations with respect to Novartis ranking for the 2024 Access to Medicines Index (ATMI)? Can you remind us why your ATMI ranking declined in 2022 vs. 2021?

- We are pleased to have had a leading ranking in ATMI over the last decade. We believe that this is a by-product of our consistent efforts towards improving access to medicines in LMICs.
- Our 2022 ATMI rating declined from second to fourth due to the impact of a legacy Alcon issue that occurred between 2011 and 2016 (Alcon was spun off in 2019).
- We recently submitted our responses for the 2024 ATMI cycle, with results expected in Q4 2024.
- Novartis remains dedicated to providing access to patients in every corner of the world, as evidenced by our reaching 284m patients globally with our medicines in 2023, including 33.2m through access approaches in LMICs.⁷

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Human capital

Question

06

Can you provide an update on your Transformation for Growth initiative?

Response

- In recent years, we have evolved from being a diversified healthcare conglomerate to a pure-play innovative medicines company. In 2022, we introduced a new operating model to make our organization more agile and efficient in support of our strategy.
- The re-organization involved difficult decisions, including workforce reductions, and caused uncertainty for many of our employees. We navigated these changes to implement the new structure as quickly as possible, ensuring that we took the appropriate steps to support our people compassionately. We established six basic principles to manage the transition, including fairness in decision-making, compliance with local legal requirements and equal opportunities in connection with applying for other available roles. Those affected had access to various support programs to help them transition to new roles, both internally and externally.
- The Transformation for Growth initiative is on track for completion in 2024. While we initially saw a decrease in employee engagement scores in 2022, current scores have increased (as of Q2 2024) and now exceed external benchmarks.

Nature and environment

07

Could you provide more details about your nature and biodiversity strategy?

- We are progressing on our existing commitments on:
 - **Climate:** Near-term and long-term science-based greenhouse gas emissions reduction targets, including net-zero by 2040 → [view more](#).
 - **Water:** 50% reduction in water use by 2025 (2016 baseline) and water neutral by 2030⁸; no water quality impacts from manufacturing effluents by 2025 and enhanced water quality wherever we operate by 2030.
 - **Waste:** 50% in waste disposal by 2025 (2016 baseline) and plastic neutrality by 2030.
- To help us better understand our impacts and dependencies on nature, we conducted a technical assessment, following the TNFD LEAP⁹ approach. The scope includes direct operations and upstream supply chains.
- Based on this analysis, we plan to develop our approach to biodiversity by the end of 2024.

08

What are the specific steps that you are taking to reduce environmental impact of active pharmaceutical ingredients (API) at contract manufacturing sites?

- We have increased engagement with our manufacturing suppliers in managing their impact on aquatic environments, including:
 - Training and capability building: We conduct training for our API supplier sites on wastewater management.
 - Technical support: We assist in performing wastewater effluent risk assessments in alignment with industry best practices, e.g. PSCI water quality maturity assessment.
 - Monitoring: We regularly monitor and promptly address any incidents.
- 88% of our high-risk suppliers met our water quality standards in 2023 vs. 26% in 2022.

Content

Click below to navigate through the document

Welcome

Intersection of climate change and human health

Positive Ph2/3 CALINA study data for malaria treatment in babies <5kg

Novartis climate targets validated by SBTi

Novartis approach to human rights and the EUCSDDD

Top 10 questions from shareholders

Product quality and animal welfare

Question

Response

09

We appreciate your transparency in reporting the number of recalls in your integrated report. Can you share your approach towards product safety and quality? What was the driver of the class 1 product recall in 2023?

- Maintaining the quality and safety of our medicines is fundamental to our core business. We apply strict quality and safety standards and contractually oblige third parties to follow our standards on quality with robust quality processes. Audits and inspections are conducted to verify compliance with regulatory requirements and guidelines.
- We obtained ISO 9001:2015 certification in 2023, an internationally recognized benchmark for quality management systems.
- In 2023, the class 1 recall concerned Sandimmune® Oral Solution which was distributed in US. The recall was caused by crystallization of active substance in the product. The specific formulation has been discontinued and is no longer on the market. Sandimmune® Capsules and Neoral® Oral Solution are the available alternatives to ensure continued treatment for patients.

10

Following the 2022 Modernization Act 2.0 in preclinical trials, can you share your efforts in animal welfare?

- Our R&D sites and suppliers adhere to our Animal Welfare policy, which includes a 3Rs program aiming to 1) replace animal use with alternative non-animal methods, 2) reduce the use of animals in clinical trials through improved study methods, and 3) refine study methods to enhance the animal experience.
- Our 3Rs Granting Program provides funding to scientists for the advancement of reduction and replacement technologies. Some examples of advancements in non-animal methods for screening new therapeutic compounds include: Brain cells cultured in the lab, evaluation of liver-on-a-chip technology, and employment of 3D gastrointestinal organoids.
- We reduced the number of animals utilized in our clinical trials by 30% from 2018 to 2022.
- All of our animal in-vivo research sites have obtained independent, voluntary and internationally recognized gold-standard accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care.

7. Includes patients reached with medicines through Novartis Global Health, as well as patients reached through support programs, emerging market brands and donations. 8. All Novartis sites to reduce water consumption in all areas and to be water neutral in water-stressed regions by not depleting local water reserves. Water-stressed regions are determined using the WWF Water Risk Filter. 9. Task Force on Nature-related Financial Disclosures: Locate, Evaluate, Assess, Prepare.