

Second-Party Opinion

Novartis Sustainability-Linked Notes



Evaluation Summary

Sustainalytics is of the opinion that the Novartis Sustainability-Linked Notes align with the Sustainability Linked Bond Principles 2020 and considers the KPIs to be relevant and material to the issuer and the SPTs to be credible and impactful. This assessment is based on the following:



Selection of Key Performance Indicators (KPIs) Novartis has selected two internally tracked KPIs, (i) Strategic Innovative Therapies Patient Reach and (ii) Flagship Programs Patient Reach, for the Sustainability Linked Notes (SLN). Sustainalytics considers the KPIs chosen to be relevant and material for the Group, and further considers the Flagship Programs (FP) KPI to be clear and credible. Sustainalytics notes the significant discretion of Novartis' Executive Committee members in the selection of Strategic Innovative Therapies (SIT) considered in its SIT KPI to be a limitation.



Calibration of Sustainability Performance Targets (SPTs) Novartis has established SPTs (2025 Patient Access Targets) to increase its KPI performance by 200% for the SIT KPI and 50% for the FP KPI by 2025. Sustainalytics considers the SPTs to be aligned with the issuer's sustainability strategy. Sustainalytics further considers the SPTs for both the FP KPI and SIT KPI to represent material improvements based on past performance, and to support access to medicine in low- and middle- income countries.



Bond Characteristics Novartis has disclosed that should the Group (along with its subsidiaries) fail to achieve one or both of the 2025 Patient Access Targets (SPTs), the associated coupon rate will increase by 0.25% commencing with the first interest payment date after 31 December 2025.



Reporting Novartis commits to report on an annual basis on its performance on the KPIs in its Annual Society ESG Report, which is aligned with market expectations.



Verification Novartis commits to have external limited assurance conducted on its KPI performance for the baseline and at the date of the SPTs' deadline in December 2025, which is aligned with market expectations.

Evaluation date	September 2020
Issuer Location	Luxembourg, Grand Duchy of Luxembourg

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Introduction

Novartis AG and its consolidated affiliates (“Novartis,” or “the “Group”) is a global pharmaceutical Group headquartered in Basel, Switzerland. Novartis develops and manufactures medicines through two global operating divisions: Innovative Medicines and Sandoz. The Group generates the majority of its total revenue from its Innovative Medicines division, which is organized into two global business units: Novartis Oncology and Novartis Pharmaceuticals. Novartis Pharmaceuticals consists of the following global business franchises: ophthalmology, neuroscience, immunology, hepatology and dermatology, respiratory, cardiovascular, renal and metabolism, and established medicines. Novartis’ main markets are Europe (38% of FY2019 sales) and the United States (34%), followed by Asia, Africa, Australia (21%) as well as Canada and Latin America (7%).

Novartis Finance S.A. (issuer), a subsidiary of the Group, intends to issue Sustainability-Linked Notes (SLN) in September 2020 where the coupon rate of the notes is tied to the achievement of the Group’s Sustainability Performance Targets (referred to as 2025 Patient Access Targets). Its two Key Performance Indicators (KPI) are linked to patient reach of the Group’s Strategic Innovative Therapies and Flagship Programs¹ in certain low and middle income countries. The KPIs apply to all companies under the Group.

The Group has engaged Sustainalytics to review the SLN and provide an opinion on the alignment of the notes with the Sustainability-Linked Bond Principles (SLBP).²

As part of this engagement, Sustainalytics engaged various members of the Group’s management team, who provided information to further understand its KPIs and related SPTs, the Group’s sustainability strategy, as well as the processes that it has in place to verify its performance in relation to the SPTs. Sustainalytics also reviewed relevant public documents.

Scope of work and limitations

Sustainalytics’ Second-Party Opinion reflects Sustainalytics’ independent³ opinion on the alignment of the reviewed SLN with the Sustainability Linked Bond Principles 2020, as administered by ICMA.

As part of this engagement, Sustainalytics exchanges information with various members of Novartis’ management team to understand the sustainability impact of their business processes and SPTs, as well as reporting and verification processes of aspects of the SLN. Novartis representatives have confirmed that:

- (1) They understand it is the sole responsibility of Novartis to ensure that the information provided is complete, accurate or up to date;
- (2) They have provided Sustainalytics with all relevant information; and
- (3) Any provided material information has been duly disclosed in a timely manner.

Sustainalytics also reviewed relevant public documents and non-public information. This document contains Sustainalytics’ opinion of the Bond and should be read in conjunction with the Bond Documents. Any update of the present Second-Party Opinion will be conducted according to the agreed engagement conditions between Sustainalytics and Novartis. Sustainalytics’ Second-Party Opinion, while reflecting on the alignment of the Bond with market standards, is no guarantee of alignment nor warrants any alignment with future versions of relevant market standards. Furthermore, Sustainalytics’ Second-Party Opinion addresses the anticipated SPTs of KPIs but does not measure the KPIs. The measurement and reporting of the KPIs is the responsibility of the Bond issuer. No information provided by Sustainalytics under the present Second-Party Opinion shall be considered as being a statement, representation, warrant or argument either in favor or against, the truthfulness, reliability or completeness of any facts or statements and related surrounding circumstances that Novartis has made available to Sustainalytics for the purpose of this SPO.

¹ Novartis’ flagship programs focus on leprosy, malaria, sickle cell disease and Chagas disease. Source: Corporate website, Novartis, accessed August 2020: <https://www.novartis.com/news/novartis-corporate-fact-sheet/global-health-corporate-responsibility#:~:text=For%20our%20four%20flagship%20programs,efforts%20to%20reinforce%20healthcare%20systems>.

² The Sustainability Linked Bond Principles (SLBP) were launched by ICMA in June 2020. They are administered by the ICMA and are available at: <https://www.icmagroup.org/assets/documents/Regulatory/Green-Bonds/June-2020/Sustainability-Linked-Bond-Principles-June-2020-100620.pdf>

³ When operating multiple lines of business that serve a variety of client types, objective research is a cornerstone of Sustainalytics and ensuring analyst independence is paramount to producing objective, actionable research. Sustainalytics has therefore put in place a robust conflict management framework that specifically addresses the need for analyst independence, consistency of process, structural separation of commercial and research (and engagement) teams, data protection and systems separation. Last but not the least, analyst compensation is not directly tied to specific commercial outcomes. One of Sustainalytics’ hallmarks is integrity, another is transparency.

Sustainalytics' Opinion

Section 1: Sustainalytics' Opinion on the Alignment of Novartis' Sustainability-Linked Notes with the Sustainability-Linked Bond Principles.

Sustainalytics is of the opinion that the Sustainability-Linked Notes align with the five core components of the Sustainability-Linked Bond Principles 2020 (SLBP). The KPIs and SPTs used by Novartis are defined in Tables 1 and 2 below.

Table 1: KPI definitions

KPI	Definition
Strategic Innovative Therapies Patient Reach	<p>Number of patients reached annually across Low- and Middle-Income Countries (LMICs)⁴ with Strategic Innovative Therapies (SIT)</p> <p>"Strategic Innovative Therapies" are defined as non-generic therapies commercialized by Novartis' "Innovative Medicines" division and approved by a competent member of the Executive Committee of Novartis based on factors including, but not limited to:</p> <ul style="list-style-type: none"> (i) patient impact, e.g. the treatment addresses a significant global disease burden, (ii) commercial viability, e.g. the treatments represents a sustainable commercial opportunity, and (iii) innovative standing, e.g. the treatment is either comparable or exceeds the existing standard of care. <p>Novartis clarified to Sustainalytics that all three factors will be considered in the selection of SITs. In addition, Novartis clarified that the decision whether a treatment is added to the list of SITs is unrelated to the Group's efforts to expand patient reach in LMICs.</p> <p>Patient reach is calculated as annual product sales volume (in units by brand and country) / volume per patient (an assumed standard number of units of the relevant therapy used by the average patient in any fiscal year, determined based on certain assumptions with regard to compliance, treatment duration, and average dose per patient). The assumptions used are specific for each brand. The KPI will be calculated as the number of patients reached through the eligible medications in the eligible countries per year added up for all brands under consideration.</p>
Flagship Programs Patient Reach	<p>Number of patients reached annually across LMICs through Novartis' Global Health Flagship Programs</p> <p>Novartis Flagship Programs includes treatments for leprosy, malaria, sickle cell disease, and a potential new treatment for Chagas disease.</p> <p>Patient reach is calculated as annual product sales volume (in units by brand and country) / volume per patient (an assumed standard number of units of the relevant therapy used by the average patient in any fiscal year, determined based on certain assumptions with regard to compliance, treatment duration, and average dose per patient). The assumptions used are specific for each brand. The KPI will be calculated as the number of patients reached through the eligible medications in the eligible countries per year added up for all brands under consideration.</p>

⁴Please refer to Annex 1 for a list of countries considered Low- and Middle-Income Countries (LMICs) by Novartis.

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Table 2: SPTs and Past Performance

KPI	2017	2018	2019 (baseline)	SPT 2025
Strategic Innovative Therapies Patient Reach (annually in millions)	0.238	0.383	0.548	200% increase by 2025, to 1.64 million patients
Flagship Programs Patient Reach (annually in millions)	39.589	28.509	15.069	50% increase by 2025, to 22.60 million patients

1) Selection of Key Performance Indicators (KPIs)

Definition and methodology of KPIs

- Novartis' Sustainability-Linked Notes include two KPIs, both of which address access to medicine in Low- and Middle-Income Countries (LMICs):
 - The list of countries and territories defined as LMICs is provided in Annex 1. Sustainalytics positively notes that while treatments partially overlap in both KPIs, Novartis confirmed that any units of a particular treatment sold will only be counted under one KPI.
 - Novartis confirms that for any treatments to be distributed into any country or territory, Novartis must have received market authorization from the competent healthcare authorities in the respective LMICs.
- Strategic Innovative Therapies (SIT) Patient Reach:
 - The SIT Patient Reach KPI measures the patients reached annually with SIT and includes exclusively non-generic treatments as approved by a competent member of the Group's Executive Committee based on the factors listed in Table 1 above.
 - Sustainalytics positively views the intention of Novartis to increase the number of patients in LMICs receiving benefits from its new treatments. While Novartis has confirmed to Sustainalytics that its past performance on this KPI was calculated based on the same set of treatments as the baseline, there is a possibility that the set of treatments for the SIT KPI may change over time to include new treatments, which will have an impact on the Group's future performance on this KPI. This means that a clear and consistent application of the selection criteria is critical to ensuring that the measurement of this KPI remains meaningful. Sustainalytics positively notes that Novartis clarified that it does not expect any of the Established Medicines currently commercialized by the Group's Innovative Medicines division to be selected as SIT, and that the process of approving a particular therapy as an SIT is unrelated to the Group's efforts to expand patient reach in LMICs. However, Sustainalytics considers the members of the Group's Executive Committee to have a significant amount of discretion in regard to how the factors mentioned in Table 1 are interpreted and taken into consideration when choosing whether a treatment is considered an SIT, which is considered a limitation.
- Flagship Programs (FP) Patient Reach:
 - The FP Patient Reach KPI measures the patient reach of Novartis' FP, which focuses exclusively on the treatment of leprosy, malaria, sickle cell disease, and Chagas disease. Sustainalytics notes that the KPI also includes generic treatments for leprosy.
- Novartis' methodology to calculate Patient Reach is the aggregated number of annual product sales volume booked/ volume per patient. While Novartis has confirmed that data on sales volume is a readily available number, which is updated monthly, Sustainalytics notes that the figures provided to calculate the performance for both KPIs require the Group's responsible officers to make certain assumptions and estimates with an unknown degree of subjectivity. The sales volume numbers may include treatments that are held in stock (or supplied to their respective markets) and have not yet reached patients.

Relevance and Materiality of KPIs

- Sustainalytics considers the issue of "Access to Medicines", defined as medicines being widely/equitably available and affordable,⁵ as a highly relevant and material issue for Novartis, as ensuring broad access to health products is considered key for pharmaceutical companies to reach their customer base and address unmet medical needs. In addition, Novartis' own materiality assessment, conducted in 2017 with input from

⁵ WHO, Access to essential medicines 2010; https://www.who.int/healthinfo/systems/WHO_MBHSS_2010_section4_web.pdf?ua=1, WHO Access to medicines Statement, 13 March 2009; <https://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/>

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internal and external stakeholders, identified Access to Medicines as the most material issue for the Group. Moreover, in 2019 Novartis' introduced new management targets directly related to access to medicines, namely (i) increasing the number of patients reached in low- and middle-income countries with strategic brands in the Innovative Medicines portfolio by 20% in 2020 compared to 2019 and (ii) launch Novartis Access⁶ in 30 countries.

- Sustainalytics notes that access to a medicine depends on the product's availability and its pricing model for targeted market segments. Availability is determined by factors such as registration and supply, which can be achieved through partnerships in the supply chain to guarantee high distribution coverage and product adoption, through investments in healthcare infrastructure and capacity building/training for healthcare workers.^{7,8} While new medicines can help control increasing costs within a healthcare system, they are often expensive for patients where public pharmaceutical benefit schemes do not exist or where private health insurance is unavailable.⁹ Sustainalytics acknowledges that approved novel drug therapies are important for advancing patient care, however pose limitations in terms of addressing the unmet needs of patients given that cost of innovative treatments is often a key barrier to access. Many new medicines result in high out-of-pocket expenditure in most LMICs.¹⁰ Given the resulting challenges in relation to vulnerable populations' access to medicines, different access strategies have been developed by pharmaceutical companies, such as establishing relationships with relevant stakeholders (e.g. payors, hospitals, specialists, and regulatory authorities), adjusting pricing to local ability to pay, and capacity building for health care personnel. A lack of adjusted pricing under strong intellectual property (IP) protection may hinder market entrance and has led countries such as India and Brazil to impose compulsory licenses to allow the production of cheaper generics without requiring the consent of the patent holder ("TRIPS compulsory licensing flexibility").¹¹
- Sustainalytics welcomes Novartis' confirmation that it aims to ensure affordability through a fair (equitable) pricing model that also considers the most vulnerable population of the respective markets, but encourages the Group to further disclose details on how affordability is ensured, particularly for patented medicines/therapies in the defined LMICs.

Ability to be benchmarked

Sustainalytics notes that the selected KPIs do not lend themselves well to comparison against external benchmarks or peer performance. While KPIs that can be benchmarked are generally preferable, Sustainalytics recognizes that standardized metrics to measure patient reach do not exist, and that each pharmaceutical Group defines KPIs and targets to improve access to medicine slightly differently.¹² Sustainalytics views positively Novartis' efforts to advance the development and use of metrics to measure patient reach and has commented further in the section below on Novartis' approach to benchmarking.

Overall assessment

In Sustainalytics' opinion the selected KPIs are relevant and material to the Group. Sustainalytics considers the definition of the FP KPI to be clear and credible, but notes the significant discretion of Novartis' Executive Committee members in considering factors such as patient impact and innovative standing, as part of their selection of Strategic Innovative Therapies (SIT) for its SIT KPI, to be a limitation.

⁶ Novartis Access is a programme in which Novartis offers its Access portfolio of on- and off-patent medicines addressing key noncommunicable diseases (NCDs) as a basket to governments, NGOs and other institutional customers in lower-income countries at a price of USD 1 per treatment per month. Source: <https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/novartis-social-business/novartis-access>

⁷ https://accessmedicinefoundation.org/media/uploads/downloads/5d93329e141cb_Access-to-Medicine-Index-10-Year-Analysis.pdf

⁸ <https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full>

⁹ GRI: Sustainability Topics for Sectors: What do stakeholders want to know? PHARMACEUTICALS, BIOTECHNOLOGY AND LIFE SCIENCE; <https://www.globalreporting.org/resource/library/46-Pharmaceuticals.pdf>

¹⁰ WHO, Essential medicines and health products, accessed August 2020: <https://www.who.int/medicines/areas/access/en/>

¹¹ WHO Bulletin of the World Health Organization, accessed August 2020: <https://www.who.int/bulletin/volumes/91/7/12-115865/en/>

¹² For this comparison, Sustainalytics used the following sources: Johnson & Johnson disclosed goals for 2020 to Deliver HIV/AIDS therapy access to a cumulative 130,000 adults and 5,000 children, Deliver access to MDR-TB therapy to a cumulative 200,000 patients, potentially curing 157,000 people with MDR-TB of the disease. Support the delivery of 6 million eye care screenings to underserved children and corrective treatments (spectacles) as needed to 100,000 underserved children.

<https://www.jnj.com/document/johnson-johnson-health-for-humanity-2020-goals?id=0000015c-adde-d4cb-a5fd-efdef8110000>, and GSK set the target to Use access strategies to reach 800 million underserved people in developing countries with our products by 2025 <https://us.gsk.com/en-us/responsibility/#tab-1-2>

2) Calibration of Sustainability Performance Targets (SPTs)

Alignment with issuer's sustainability strategy

- Novartis has set the following SPTs ("2025 Patient Access Targets") for its two KPIs:
 - For the SIT KPI, a 200% increase in number of patients reached annually by 2025, reaching 1.6 million patients;
 - For the FP KPI, a 50% increase in number of patients reached annually by 2025, reaching 22.6 million patients.
- Sustainalytics considers the SPTs to be strongly aligned with Novartis' sustainability strategy (please refer to Section 2 for analysis of the credibility of Novartis' sustainability strategy). In 2019, the Group launched a new three-year Global Health & Corporate Responsibility (GH&CR) strategy in which three of the five pillars relate to patient access and to the treatments included in the KPIs.¹³ These pillars are:
 - Guide the implementation of the Novartis Access Principles in the areas of research and development (R&D), affordability and pricing, and health system strengthening;
 - Drive end-to-end strategies for the elimination or control of four diseases where there has been market failure and little investment in R&D: malaria, leprosy, sickle cell disease and Chagas disease; and
 - Implement a new strategy for Sub-Saharan Africa focused on reaching more patients and expanding the availability of Novartis portfolio of medicines.¹⁴

In addition, the Group has set management targets related to patient reach in LMICs and addressing access to non-communicable diseases.¹⁵
- Novartis' overall approach to increasing patient access is based on the Novartis Access framework, which includes a range of different access models, such as differential pricing, structured donation programmes and non-exclusive voluntary licensing.¹⁶

Strategy to achieve the SPTs

- Novartis intends to achieve its SIT SPT through five main strategies:
 - (i) The introduction of specific requirements in its drug development processes that are aimed to increase the focus of relevant teams on positive health impact in LMICs in terms of affordability, health system strengthening, and adaptive research and development;
 - (ii) Expanding its use of emerging market brands (EMB), which include the same treatment as sold in established markets without deviation of formula, but commercialized under the name of a local brand. An example of such an initiative is the Group's recently announced agreement with the Clinton Health Access Initiative;¹⁷
 - (iii) Developing effective affordability strategies by accelerating a societal shift to value-based healthcare, which includes tailored pricing strategies by the Group along with efforts to change governmental and insurance regulated pricing schemes. Novartis has a four-tiered pricing approach, in which it categorizes countries into four tiers based on microeconomic factors and access challenges;
 - (iv) Strengthening local healthcare systems through the provision of training to healthcare workers; and
 - (v) Lowering distribution costs through, for example, incorporating e-commerce and online pharmacies.
- In addition, the Group has indicated that the target of 50% increase in the FP KPI is set mainly on the basis of:
 - (i) The Group's new Sub-Saharan Africa Strategy and its newly created Sub-Saharan Africa unit with its mandate to maximize patient reach across the full income pyramid by focusing on tiered pricing models, competitiveness in tenders and scaling healthcare systems strengthening activities as well as affordability strategies;
 - (ii) Developing a potential new treatment for Chagas disease which is currently still in trial phase;¹⁸
 - (iii) Increasing the number of patients reached through its new malaria treatment despite increased competition;

¹³ Corporate website, Novartis, accessed August 2020: <https://www.novartis.com/news/global-health-corporate-responsibility>

¹⁴ Novartis Society Report 2019: <https://www.novartis.com/sites/www.novartis.com/files/novartis-in-society-report-2019.pdf>

¹⁵ Corporate website, Novartis: Targets and Results, accessed August 2020: <https://www.novartis.com/our-company/corporate-responsibility/reporting-disclosure/targets-results#ui-id-1=0>

¹⁶ Access to medicine Foundation, First Independent Ten-Year Analysis; Are pharmaceutical companies making progress when it comes to global health? May 2019: https://accesstomedicinefoundation.org/media/uploads/downloads/5d93329e141cb_Access-to-Medicine-Index-10-Year-Analysis.pdf

¹⁷ Clinton Health Access initiatives, New agreements to lower prices and increase access to lifesaving cancer treatment in sub-Saharan Africa, 29 June 2020: <https://www.clintonhealthaccess.org/agreements-to-increase-access-to-cancer-treatment-in-africa/>

¹⁸ Corporate website, Novartis, accessed August 2020: <https://www.novartis.com/our-impact/global-health/chagas-disease>

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- (iv) Increasing access for new therapies approved in November 2019 which reduces the frequency of vaso-occlusive crises, or pain crises¹⁹ for sickle cell patients, as part of its Africa sickle cell disease program; and
- (v) Supporting the development of an AI-enabled digital health tool to aid in the early detection of leprosy.

Ambitiousness, Baseline and Benchmarks

- Novartis used its KPI performance in 2019 as a baseline for setting its SPTs and discloses the past performance of both indicators for the last three years (see Table 2 for more details) The Group confirmed that it will rely on the same definitions and methodology to measure future performance against its SPTs as it used to measure past performance on these KPIs.
- According to the Group, the SIT KPI showed a 61% increase between 2017 and 2018 and a 43% increase between 2018 and 2019. Novartis has confirmed that it does not expect any of the Established Medicines currently commercialized by the Group's Innovative Medicines division to be selected as SITs and that the process of approving a particular therapy as an SIT is unrelated to the Group's efforts to expand patient reach in LMICs. Based on this confirmation, Sustainalytics considers Novartis SIT KPI to increase patient reach by 200%, from 0.5 million in 2019 to 1.6 million in 2025, to be a material improvement, given the Group will either need to significantly increase the patients reached with the existing treatments covered under the SIT KPI or successfully expand patient reach in LMICs with future additions to its portfolio of approved SIT. Regarding the FP KPI, past performance shows a decline in patients reached of 28% between 2017 and 2018 and a decline of 47% between 2018 and 2019. Thus, Sustainalytics considers the SPT of a 50% increase in patient sales to be a material improvement.
- Novartis maintains the right to include lost product sales volumes, up to 20%, that are due to force majeure events or extraordinary, exceptional, one-time or unusual events or circumstances. Novartis does not provide further information on circumstances or events in which the KPIs performance may potentially be recalculated.

Overall Assessment

Sustainalytics considers Novartis' SPTs to be consistent with its overall sustainability strategy and considers its strategy to achieve the SPTs and benchmarks to be credible. Sustainalytics positively notes the Group's use of recent data for its baseline and its defined timeline to achieve the targets. In addition, while no external benchmark for access to medicines in LMICs exists, Sustainalytics considers the SPTs set for the FP KPI and SIT KPI to present material improvements based on past performance and positively notes that both SPTs need to be met.

3) Bond characteristics

Novartis has disclosed that should it or its subsidiaries fail to achieve one or both of the 2025 Patient Access Targets (SPTs), the associated coupon rate will increase by 0.25% commencing with the first interest payment date after 31 December 2025. While no downward adjustment of the coupon rate, in the event that both of the SPTs are met, Sustainalytics positively notes that both SPTs need to be met to avoid an increase in the coupon rate.

4) Reporting

Novartis commits to report on an annual basis on its performance on the KPIs, and expects to include the relevant figures in its Novartis Society ESG Reports,²⁰ which is aligned with the SLB Principles. Sustainalytics further encourages the Group to publish and keep readily available and easily accessible any information enabling investors to monitor the level of ambition of the SPTs, particularly in relation to the SIT KPI given the flexible nature of this KPI.

5) Verification

Novartis commits to having an external verifier provide limited assurance on the published KPI performance figures for each fiscal year ending 31 December from 2020 up to and including 2025, which is aligned with the SLB Principles on verification.

¹⁹ Corporate website, Novartis, accessed August 2020 : <https://www.novartis.com/news/media-releases/new-novartis-medicine-adakveo-crizanlizumab-approved-fda-reduce-frequency-pain-crises-individuals-living-sickle-cell-disease#:~:text=Basel%2C%20November%2015%2C%202019%20%E2%80%93,older%20with%20sickle%20cell%20disease.>

²⁰ Novartis in Society ESG Report 2019: <https://www.novartis.com/our-company/corporate-responsibility/corporate-responsibility-reporting-and-disclosure/novartis-society-report>

Alignment with Sustainability Linked Bond Principles 2020

Sustainalytics has determined that the Novartis September 2020 SLN align with the five core components of the Sustainability Linked Bond Principles (2020).

Section 2: Assessment of Novartis' Sustainability Strategy

Credibility of Novartis sustainability strategy

Novartis has a longstanding commitment to patient access and innovative medicine, illustrated by both its dedicated business segments and strategies that position patient access as a guiding principle for its business proposition and strategies. Novartis was recognized by the Access to Medicine Index 2018 ranking as second amongst the 20 global pharmaceutical companies assessed,²¹ up from rank three in 2016.²² The Group has also consistently invested in projects and initiatives that the global health community has identified as key priorities. To this end, the Group was the first pharmaceutical to publicly commit to establishing access plans for all innovative new medicines.²³ Novartis' Access Principles aim to integrate access-oriented thinking across the Group's overall pipeline, focusing on Research and Development, Affordability, and Strengthening of Healthcare Systems.^{24, 25} The Novartis Access Program for its part is designed to increase access to affordable treatments for key non communicable chronic diseases²⁶ to patients in lower-income countries.²⁷ Novartis Access is offered as a portfolio or basket of on- and off-patent medicines²⁸ addressing key noncommunicable diseases (NCDs), directly to governments, NGOs or other institutional customers in lower income countries.

In 2019, Novartis introduced new management targets to include environmental, social and governance (ESG) topics, including themes such as environmental sustainability, pricing and access to medicines, global health, ethics, and risk.²⁹ The two targets outlined are namely, for '100% of new products launched to include an access strategy', and the 'Launch [of] Novartis Access in 30 countries over the coming years'.³⁰ Novartis discloses that its medicines "reach nearly 800 million people globally,"³¹ that it reached 10,503 patients through managed access programs in 2019, achieving an 81% increase in pre-approval access to Novartis medicines in 2019 compared to 2018 and that it reached 16 million people through access programs.³²

Given Novartis' quantitative goals and corporate-wide strategy, Sustainalytics is of the view that the targets, KPIs and investments identified as part of this issuance, as referenced in Section 1, will further support the Group advance its sustainability strategy.

²¹ The Access to Medicine Index evaluates companies' performances across seven areas that impact access to medicine.

²² Access to Medicine Index 2016: https://accesstomedicinefoundation.org/media/uploads/downloads/5bc5edde7a277_Access-to-Medicine-Index-2016.pdf

²³ Access to Medicine Index p. 7, 21 available at

https://accesstomedicinefoundation.org/media/uploads/downloads/5e27136ad13c9_Access_to_Medicine_Index_2018.pdf

²⁴ Corporate website Novartis, accessed August 2020: <https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/access-principles>

²⁵ Ibid, p.22

²⁶ The key noncommunicable diseases identified by Novartis as part of its Novartis Access program are cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer. Corporate website Novartis, accessed August 2020:

<https://www.novartis.com/sites/www.novartis.com/files/factsheet-novartis-access.pdf>

²⁷ Corporate website Factsheet Novartis Access, accessed August 2020: <https://www.novartis.com/sites/www.novartis.com/files/factsheet-novartis-access.pdf>

²⁸ Corporate Website Novartis: 'The products included in the portfolio have been selected based on three criteria: significant health needs, medical relevance, and lack of local access programs. The portfolio aims to offer various treatment options, including well-proven and standard first-line treatments as well as some of the latest treatment choices. Most of the medicines in the portfolio are either on or belong to a class on the World Health Organization's Model List of Essential Medicines and are among the most commonly prescribed medicines,' accessed August 2020:

<https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/novartis-social-business/novartis-access>

²⁹ Corporate website Novartis, accessed August 2020: <https://www.novartis.com/our-company/corporate-responsibility/reporting-disclosure/targets-results#ui-id-1=1>

³⁰ Corporate website Novartis, accessed August 2020: <https://www.novartis.com/our-company/corporate-responsibility/reporting-disclosure/targets-results#ui-id-1=1>

³¹ Corporate website Novartis, accessed August 2020: <https://www.novartis.com/investors/company-overview/novartis-fact-sheet>

³² Corporate website Novartis, accessed August 2020: <https://www.novartis.com/our-focus/patients-caregivers>

Novartis' environmental and social risk management

While Sustainalytics recognizes that the Group's defined targets are impactful, we acknowledge that providing access to medicines can be hampered by risk associated with the development, distribution, and commercialization of treatment. In the following section Sustainalytics comments on Novartis' ability to mitigate such potential risks.

Novartis counts on leading access to medicine programs, including initiatives in countries with low and middle-income economies, and initiatives that address neglected tropical diseases and other communicable diseases. Sustainalytics notes that the Group has been involved in pricing controversies in last decade, including price setting and increases and rulings against ever greening.³³ Sustainalytics notes this litigation is no longer outstanding, and that the Group today counts on strong policies and programs to ensure access to its medication. However, given the recurrence of related incidents, Sustainalytics encourages the Group to continuously ensure effective implementation of its policies and programs and to actively disclose how prices are set for the treatments falling into the KPIs.

As part of a heavily regulated industry, pharmaceutical companies are subject to scrutiny on a range of topics related to business ethics, including political lobbying, anti-competitive behavior and tax practices, as well as ethical conduct related to pharmaceutical product development, and intellectual property (IP) rights of products can result in so-called "patent wars". Sustainalytics notes positively that Novartis counts on a strong business ethics program, which includes annual training of employees on the Group's code of conduct, measures to deter non-compliance and reduce exposure to unethical opportunities, incident investigation and corrective actions. The Group counts on a dedicated Chief Ethics, Risk & Compliance Officer, as a member of the Executive Committee. While noting the Group's strong policies as described,³⁴ Sustainalytics recognizes Novartis has been involved in controversies in relation to its payment to politically linked individuals in the United States,³⁵ and the bribery of medical staff. Sustainalytics positively notes the Group's management improvements made over the last three fiscal years, together with the lack of new bribery allegations over the same time period, which provide assurance that the Group is well prepared to prevent similar issues in the future.

Overall, Sustainalytics considers that the Group has strong management programs and policies to mitigate risks that could hamper access to medicine or the achievement of the specified Patient Reach SPTs and encourages Novartis to continuously ensure the implementation of these policies and programs.

Section 3: Impact of the SPTs chosen

Guaranteeing access to medicines remains a key challenge for the pharmaceutical industry globally. Access to medicines is recognized as one of the key objectives of the Sustainable Development Goals (SDG 3) with 2 billion people globally being unable to access essential medicines, resulting in millions of deaths in low- and middle-income countries each year from diseases because the vaccines, medicines and diagnostic tests that they need are either unavailable or unaffordable.³⁶ More than 100 million people are being pushed into extreme poverty due to healthcare payments.³⁷ As such, there is a strong need for increased access to medicines in low-middle income countries, given unaffordable prices for the majority of the population especially in least developed countries and increasingly in middle-income countries.³⁸ The Access to Medicine Foundation has found that people in low- and middle-income countries carry a disproportionate share of the global burden, defined by "how severely a population is impacted by a disease or condition", from the diseases in scope of the Access to Medicine Index.³⁹

³³ Evergreening is the practice of patenting "new inventions" that are limited to slight modifications of old drugs. Source: Roger Collier, Drug patents: the evergreening problem, CMAJ. 2013 Jun 11; 185(9): E385–E386; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/>

³⁴ Corporate website Novartis, accessed August 2020: <https://www.novartis.com/our-company/corporate-responsibility/ethics-risk-compliance>

³⁵ Financial Times, *Novartis admits \$1.2m in payments to Trump lawyer*, accessed August 2020: <https://www.ft.com/content/61e2cca8-5363-11e8-b3ee-41e0209208ec>

³⁶ Access to Medicine Index 2018:

https://accessmedicinefoundation.org/media/uploads/downloads/5e27136ad13c9_Access_to_Medicine_Index_2018.pdf

³⁷ Access to Medicine Foundation, Access to Medicine Index 2018: <https://accessmedicinefoundation.org/access-to-medicine-index/about-the-index/why-access-matters>

³⁸ Frontiers in Medicine, 2017; Hilde Stevens and Isabelle Huys, Innovative Approaches to Increase Access to Medicines in Developing Countries, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5725781/>

³⁹ Access to Medicine Foundation, Access to Medicine Index 2018: <https://accessmedicinefoundation.org/access-to-medicine-index/about-the-index/why-access-matters>

Novartis Sustainability-Linked Notes

Given their expertise, size, resources, pipelines, portfolios, and global reach, pharmaceutical companies play a critical role in improving access to medicines, globally.⁴⁰ At the same time, investment in healthcare/innovation / R&D is limited globally, with more than 60% of R&D for diseases listed as global priorities being conducted by five companies, including Novartis.⁴¹ Moreover, the diseases that are considered under the Novartis Global Healthcare flagship programs have a particularly high occurrence in low-and middle- income countries, with 93% of the global count of malaria cases (228 million) in the African region,⁴² 6 to 7 million people worldwide infected with Chagas disease, mainly in continental Latin America,⁴⁴ and 3 million people globally with undiagnosed leprosy.⁴⁵

Given the high burden of global diseases and high occurrence of diseases treated by Novartis' flagship programme medicines in LMICs, Sustainalytics considers Novartis' KPIs and intention to achieve the associated SPTs to have the potential to positively contribute to reducing the health burden for people in need in LMICs.

Alignment with/contribution to SDGs

The Sustainable Development Goals (SDGs) were set in September 2015 and form an agenda for achieving sustainable development by the year 2030. This sustainability linked bond advances the following SDG goals and targets:

KPI	SDG	SDG target
Strategic Innovative Therapies Patient Reach	3. Good Health and Well-Being	3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
Flagship Programs Patient Reach	3. Good Health and Well-Being	3.3 By 2030, end the epidemics of aids, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

Conclusion

Novartis intends to issue Sustainability-Linked Notes which will tie the coupon rate to the achievements of the following SPTs:

- I) Increase the number of patients reached through its Strategic Innovative Therapies (SIT) to 1.6 million in 2025, a 200% increase compared to 2019;
- II) Increase the number of patients reached through its Flagship Programs (FP) to 22.6 million in 2025, a 50% increase compared to 2019.

Sustainalytics performed a review of the SLN information and considers the KPIs to be relevant and material and aligned with Novartis' sustainability strategy. While no external benchmark is used, Sustainalytics considers the past performance benchmark chosen to follow a consistent methodology. Furthermore, Sustainalytics considers the KPI for Novartis' FP to be credible and the related SPT to represent a material improvement to the baseline, but notes the significant discretion of Novartis executive committee members in the selection of its SIT KPI to be a limitation. Furthermore, Sustainalytics considers reporting and verification commitments to be aligned with market expectations.

Based on the above, Sustainalytics considers Novartis' SLN to be in alignment with the five core components of the SLBP and the prospective of achievement of the SPTs to be impactful.

⁴⁰ https://accessmedicinefoundation.org/media/uploads/downloads/5e27136ad13c9_Access_to_Medicine_Index_2018.pdf

⁴¹ Access to Medicine Index available at

https://accessmedicinefoundation.org/media/uploads/downloads/5e27136ad13c9_Access_to_Medicine_Index_2018.pdf

⁴² WHO The "World malaria report 2019" at a glance, December 2019: <https://www.who.int/news-room/feature-stories/detail/world-malaria-report-2019>

⁴³ Center for diseases control and prevention: What is Chagas disease?, February 11, 2019:

https://www.cdc.gov/parasites/chagas/gen_info/detailed.html

⁴⁴ WHO Chagas disease (American trypanosomiasis), website, accessed August 2020: https://www.who.int/health-topics/chagas-disease#tab=tab_1

⁴⁵ Lepira Org, website, accessed August 2020: <https://www.lepra.org.uk/what-we-do/leprosy>

Appendix 1

List of Countries and Territories defined as LMICs by Novartis

Afghanistan	Fiji	Nigeria
Algeria	French Guyana	North Macedonia
Angola	Gabon	Pakistan
Anguila	Gambia	Palestine
Antigua and Barbuda	Georgia	Panama
Argentina	Ghana	Papua New Guinea
Armenia	Grenada	Paraguay
Aruba	Guadeloupe	Peru
Azerbaijan	Guatemala	Philippines
Bahamas, the	Guinea	Puerto Rico
Bangladesh	Guinea-Bissau	Russia
Barbados	Guyana	Rwanda
Belarus	Haiti	Saint Kitts and Nevis
Belize	Honduras	Saint Lucia
Benin	India	Saint Martin
Bermuda	Indonesia	Saint Vincent and the Grenadines
Bhutan	Iran	Samoa
Bolivia	Ivory Coast	São Tomé and Príncipe
Bosnia-Herzegovina	Jamaica	Senegal
Botswana	Jordan	Seychelles
Brazil	Kazakhstan	Sierra Leone
British Virgin Island	Kenya	Solomon Islands
Brunei Darussalam	Kiribati	Somalia
Burkina Faso	Kosovo	South Africa
Burundi	Kyrgyzstan	South Sudan
Cabo Verde	Lao P.D.R.	Sri Lanka
Cambodia	Lebanon	Sudan
Cameroon	Lesotho	Suriname
Cayman Islands	Liberia	Syria
Central African Republic	Libya	Tajikistan
Chad	Madagascar	Tanzania
Chile	Malawi	Thailand
China, People's Republic of ⁴⁶	Malaysia	Timor-Leste
Colombia	Maldives	Togo
Comoros	Mali	Tonga
Congo Republic	Marshall Islands	Trinidad and Tobago
Costa Rica	Mauritania	Tunisia
Cuba	Mauritius	Turkey
Curacao	Mexico	Turkmenistan

⁴⁶ Only with regard to Strategic Innovative Medicines commercialized by the Group's Oncology business unit.

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Djibouti	Micronesia, Fed. States of	Tuvalu
Dominica	Moldova	Uganda
Dominican Republic	Mongolia	Ukraine
Dr Congo	Montserrat	Uruguay
Dutch Antilles	Morocco	Uzbekistan
Ecuador	Mozambique	Vanuatu
Egypt	Myanmar	Venezuela
El Salvador	Namibia	Vietnam
Equatorial Guinea	Nauru	Yemen
Eritrea	Nepal	Zambia
Eswatini	Nicaragua	Zimbabwe
Ethiopia	Niger	

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Sustainalytics

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