

# Novartis AG

Basel

Independent Assurance Report  
on Flagship Programs Patient Reach and Strategic  
Innovative Therapies Patient Reach KPIs

to the Board of Directors



# Independent Assurance Report

## on Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs to the Board of Directors of Novartis AG

### Basel

We have been engaged by Novartis AG to perform assurance procedures to provide limited assurance on Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs of Novartis AG and its consolidated subsidiaries (the "Group") for the 12 month period ended 31 December 2019 as quantified on page 16 (section "Rationale for 2025 Patient Access Targets") of the preliminary prospectus dated 15 September 2020 related to the offering of Sustainability-Linked Notes due 2028 to be issued by Novartis Finance S.A. and unconditionally and irrevocably guaranteed by Novartis AG.

The Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs were prepared by the Management of the Group based on the following Criteria:

- Flagship Programs Patient Reach is defined as aggregate Patient Reach in LMIC's with Flagship Programs:
  - Patient Reach is defined as number of patients reached with each such therapies in the relevant period and countries, calculated by dividing (a) the relevant Annual Product Sales Volume by (b) the relevant Volume Per Patient; whereas the
    - Annual Product Sales Volume is defined as the annual product sales volume during the relevant period; and the
    - Volume Per Patient is defined as the assumed standard number of units of the relevant therapy used by the average patient in any period, based on relevant assumptions, including with regard to patient compliance rate with recommended treatment regimes, average daily doses per patient, recommended and/or average days of therapy.
  - LMIC's is defined as all countries listed in Annex A within the section "Terms and Conditions of the Notes: in the preliminary prospectus dated 15 September 2020 related to the offering of Sustainability-Linked Notes due 2028;
  - Flagship Programs are defined within condition 5.2 of the section "Terms and Conditions of the Notes" of the preliminary prospectus dated 15 September 2020 (pages 34 - 35) as therapies made available for the treatment of malaria, leprosy, sickle cell disease and/or Chagas cardiomyopathy, including Coartem (including its adult and paediatric formulation), the rifampicin, dapsone and clofazimine multi-drug therapy, Hydroxyurea and Adakveo.
- Strategic Innovative Therapies Patient Reach is defined as the aggregated Patient Reach in LMIC's with Strategic Innovative Therapies:
  - Patient Reach is defined as number of patients reached with each such therapies in the relevant period and countries, calculated by dividing (a) the relevant Annual Product Sales Volume by (b) the relevant Volume Per Patient; whereas the
    - Annual Product Sales Volume is defined as the annual product sales volume during the relevant period; and the
    - Volume Per Patient is defined as the assumed standard number of units of the relevant therapy used by the average patient in any period, based on relevant assumptions, including with regard to patient compliance rate with recommended treatment regimes, average daily doses per patient, recommended and/or average days of therapy.
  - LMIC's is defined as all countries listed in Annex A within the section "Terms and Conditions of the Notes" in the preliminary prospectus dated 15 September 2020 related to the offering of Sustainability-Linked Notes due 2028
  - Strategic Innovative Therapies are defined within condition 5.2 of the section "Terms and Conditions of the Notes" within the preliminary prospectus dated 15 September 2020 (page 35) as any non-generic

therapies commercialised by the "Innovative Medicines" division that are approved as "Strategic Innovative Therapies" by a competent member of the Executive Committee

### **Inherent limitations**

The accuracy and completeness of the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach indicators are subject to inherent limitations given their nature and methods for determining, calculating and estimating such data. In addition, the quantification of the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach indicators is subject to inherent uncertainty because of incomplete knowledge on patient behavior and adherence used to determine factors related to the Volume Per Patient and the values used.

The Management of the Group calculated the Patient Reach indicators for the 12 month period ended 31 December 2019 as quantified on page 16 (section "Rationale for 2025 Patient Access Targets"), and thus our assurance report is based on historical information. Any projection of such information or our conclusion thereon to future periods is subject to the risk that changes may occur after the assurance report and the fact that data on which the KPIs are based on are potentially subject to changes.

### **Management's responsibility**

The Management of the Group is responsible for preparing the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs in accordance with the Criteria listed above. This responsibility includes the design, implementation and maintenance of the internal control system related to the preparation of the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs that are free from material misstatement, whether due to fraud or error. Furthermore, the Management of Group is responsible for the selection and application of the Criteria and adequate record keeping.

### **Independence and quality control**

We are independent of Novartis AG in accordance with the International Code of Ethics for Professional Accountants (including International Independence Standards) issued by the International Ethics Standards Board for Accountants (IESBA Code). We have fulfilled our other ethical responsibilities in accordance with the IESBA Code, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behaviour.

PricewaterhouseCoopers AG applies Swiss Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

### **Assurance practitioner's responsibility**

Our responsibility is to perform an assurance engagement and to express a conclusion on the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs. We conducted our engagement in accordance with the International Standard on Assurance Engagements (ISAE 3000) 'Assurance engagements other than audits or reviews of historical financial information. This standard requires that we plan and perform procedures to obtain limited assurance about whether the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs were prepared, in all material aspects, in accordance with the Criteria as outlined above.

Based on risk and materiality considerations, we performed our procedures to obtain sufficient and appropriate assurance evidence. The procedures selected depend on the assurance practitioner's judgement. The evidence gathering procedures were more limited than they would be on a reasonable assurance engagement and, therefore, less assurance was obtained than would be on a reasonable assurance engagement.

We performed the following procedures, among others:

- Gained an understanding of management's policies, procedures, assumptions and sources of underlying data utilized to determine the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs as of 31 December 2019; and
- Performed sampling of the underlying data.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our conclusion.

## Conclusion

Based on the work we performed, nothing has come to our attention that would cause us to believe that the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs of Novartis AG for the 12 month period ended 31 December 2019 are not prepared, in all material respects, in accordance with the Criteria.

## Restriction of use and purpose of the report

This report is prepared for, and only for, the Board of Directors of Novartis AG and Management of the Group, and solely for the purpose of reporting to it on the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs and no other purpose. We do not, in giving our conclusion, accept or assume responsibility (legal or otherwise) or accept liability for, or in connection with, any other purpose for which our report including the conclusion may be used, or to any other person to whom our report is shown or into whose hands it may come, and no other persons shall be entitled to rely on our conclusion.

We permit the distribution of our report as described on pages 16-17 (within the section “Second Party Opinions and External Verification”) of the preliminary prospectus dated 15 September 2020, in full only and in combination with the suitable Criteria, to potential investors of the Sustainability-Linked Notes due 2028 to enable the Board of Directors of Novartis AG and Management of the Group to demonstrate that they have discharged their governance responsibilities by commissioning an independent assurance report on the Flagship Programs Patient Reach and Strategic Innovative Therapies Patient Reach KPIs, without assuming or accepting any responsibility or liability to potential investors on our part. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Board of Directors Novartis AG or Management of the Group for our work or this report.

PricewaterhouseCoopers AG

/s/ Kris Muller  
Kris Muller

/s/ Jennifer Kodat  
Jennifer Kodat

Basel, 15 September 2020