

## **MEDIA & INVESTOR RELEASE**

# **Novartis receives CHMP positive opinion for Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (QVM149), a potential first-in-class inhaled LABA/LAMA/ICS combination for uncontrolled asthma**

- *CHMP positive opinion advances efforts to provide first-in-class LABA/LAMA/ICS combination for patients whose asthma is uncontrolled with LABA/ICS standard-of-care treatment in the EU.*
- *Digital companion with app and sensor that provide inhalation confirmation, medication reminders and access to objective data to better support therapeutic decisions also covered by positive opinion for Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (QVM149; IND/GLY/MF).*
- *Decision supported by robust efficacy and safety data from over 3,000 patients with asthma in Phase III IRIDIUM study, in which once-daily IND/GLY/MF demonstrated statistically significant improvements in lung function compared with once-daily IND/MF (QMF149).<sup>1</sup>*
- *In secondary analyses of the Phase III IRIDIUM study, statistically significant improvements in lung function and reductions in moderate-to-severe and severe asthma exacerbation rates were observed with high-dose IND/GLY/MF compared to high-dose Sal/Flu.<sup>1</sup>*

**Basel, May 1, 2020** — Novartis today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta<sub>2</sub>-agonist (LABA) and a high dose of an inhaled corticosteroid (ICS) who experienced one or more asthma exacerbations in the previous year. If approved, this will be the first once-daily LABA/long-acting muscarinic antagonist (LAMA)/ICS fixed-dose combination for these patients. The European Commission (EC) reviews the CHMP recommendation and usually delivers its final decision in approximately two months.

“This is an important development for patients with uncontrolled asthma because IND/GLY/MF has been shown to improve lung function and symptoms versus a LABA/ICS standard-of-care,” said Professor Huib Kerstjens, Head, Department of Pulmonology at the University Medical Center Groningen. “In secondary analyses of the Phase III IRIDIUM study

statistically significant reductions in moderate-to-severe and severe asthma exacerbation rates were observed with high-dose IND/GLY/MF compared to high-dose salmeterol xinafoate/fluticasone propionate.”

IND/GLY/MF will be administered via the dose-confirming Breezhaler® device, which enables once-daily inhalation using a single inhaler. If approved, IND/GLY/MF will be the first asthma treatment in the EU that can be prescribed together with a digital companion; a Propeller Health sensor and app custom-built for the Breezhaler® device. This companion will provide patients with inhalation confirmation, medication reminders and access to objective data that can be shared with their physician in order to help them make better therapeutic decisions.

“Today’s news is a key milestone in our journey to reimagine asthma care by bringing innovative medicines and a digital companion to patients with uncontrolled asthma,” said Linda Armstrong, MD, Respiratory Development Unit Head, Novartis Pharmaceuticals. “Once-daily IND/GLY/MF has the potential to improve asthma control for patients whose lives are still impacted by their disease, despite existing inhaled therapies. Additionally, we are pleased to bring an innovative sensor and app companion supplied with IND/GLY/MF to patients to help support enhanced adherence.”

The CHMP recommendation is based on robust efficacy and safety data from over 3,000 patients with asthma from the Phase III IRIDIUM study, in which IND/GLY/MF demonstrated statistically significant improvements in lung function compared with indacaterol acetate/mometasone furoate (IND/MF).<sup>1</sup>

In the IRIDIUM study, the key secondary endpoint was improvement in Asthma Control Questionnaire score (ACQ-7) for IND/GLY/MF versus IND/MF. Both treatments delivered clinically meaningful improvements in this measure of symptoms from baseline at Week 26, but the key secondary endpoint was not met. Among other secondary analyses, IRIDIUM explored asthma exacerbation rates, where statistically significant reductions were observed in moderate-to-severe and severe asthma exacerbation rates with IND/GLY/MF compared with an established LABA/ICS standard-of-care (twice-daily salmeterol xinafoate/fluticasone propionate). Safety findings were consistent with the known safety profiles of the monocomponents.<sup>1</sup>

Last month the CHMP also recommended the approval of Ateectura® Breezhaler® (IND/MF) as a maintenance treatment of asthma for adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta-agonists.<sup>2</sup> Novartis is committed to bringing IND/GLY/MF and IND/MF to patients, with additional regulatory filings currently underway in multiple countries, including Switzerland, Japan and Canada.

In keeping with the Novartis commitment to reduce the environmental impact of our asthma combinations, IND/GLY/MF and IND/MF will both be available in the Breezhaler® device which is hydrofluoroalkane/chlorofluorocarbon (HFA/CFC)-free.

### **About Uncontrolled Asthma**

Asthma affects an estimated 358 million people worldwide and can cause a significant personal, health and financial burden when not adequately controlled.<sup>3,4</sup> Despite current therapy, over 40% of patients with asthma at Global Initiative for Asthma (GINA) Step 3, and over 45% at GINA Steps 4 and 5 remain uncontrolled.<sup>5,6</sup> Patients with uncontrolled asthma may downplay or underestimate the severity of their disease and are at a higher risk of exacerbation, hospitalization or death.<sup>7,8,9</sup> Barriers, such as treatment mismatch, safety issues with an oral corticosteroid and ineligibility for biologics, have created an unmet medical need in asthma.<sup>10,11</sup>

### **About Enerzair® Breezhaler®**

Enerzair® Breezhaler® (QVM149; IND/GLY/MF) is intended as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a

long-acting beta<sub>2</sub>-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year. This formulation combines the bronchodilation of indacaterol acetate (a LABA) and the antimuscarinic effects of glycopyrronium bromide (a LAMA) with mometasone furoate (high-dose ICS) in a precise once-daily formulation, delivered via the dose-confirming Breezhaler<sup>®</sup> device. Glycopyrronium bromide certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei Heptares and Vectura. Mometasone furoate is exclusively licensed to Novartis from a subsidiary of Merck & Co., Inc, Kenilworth, NJ, USA, for use in IND/GLY/MF (worldwide excluding the U.S.).

The sensor for the Breezhaler<sup>®</sup> device was developed by Propeller Health and is a CE marked Medical Device, designed and licensed to Novartis exclusively for use with the Breezhaler<sup>®</sup> inhaler worldwide. The sensor includes a microchip, a microphone, Bluetooth capabilities, an antenna and a battery. The sensor does not alter the drug delivery characteristics of the Breezhaler<sup>®</sup> inhaler itself but produces a recording of each administered dose. Based on the patient's recorded medication usage, personalized content is presented within the app to help the patient better self-manage their asthma.

#### **About Ateectura<sup>®</sup> Breezhaler<sup>®</sup>**

Ateectura<sup>®</sup> Breezhaler<sup>®</sup> (QMF149; IND/MF) is the combination of indacaterol acetate and mometasone furoate intended as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with ICS and inhaled short-acting beta-agonists. IND/MF combines the bronchodilation of indacaterol acetate (a LABA) with the anti-inflammatory mometasone furoate (an ICS) in a precise once-daily formulation, delivered via the dose-confirming Breezhaler<sup>®</sup> device. Mometasone furoate is exclusively licensed to Novartis from a subsidiary of Merck & Co., Inc, Kenilworth, NJ, USA, for use in IND/MF.

#### **About the PLATINUM Clinical Development Program**

The PLATINUM program, containing over 7,500 patients worldwide, is the Novartis Phase III clinical development program supporting the development of IND/GLY/MF and IND/MF. It includes four studies: the QUARTZ study, which compared a low-dose of IND/MF with MF alone; the PALLADIUM study, which compared IND/MF with MF and salmeterol xinafoate/fluticasone propionate (Sal/Flu); the IRIDIUM study, which compared IND/GLY/MF with IND/MF and Sal/Flu; and the ARGON study, which compared IND/GLY/MF with a combination of Sal/Flu and tiotropium.

#### **About the IRIDIUM study<sup>1,12</sup>**

IRIDIUM was a Phase III, multicenter, randomized, double-blind, parallel-group study, designed to compare the efficacy and safety of IND/GLY/MF with IND/MF in patients with asthma.

The purpose of the trial was to evaluate the efficacy and safety of two different doses of IND/GLY/MF (High: 150/50/160 µg and Medium: 150/50/80 µg), versus two respective IND/MF doses (High: 150/320 µg and Medium: 150/160 µg) in patients with uncontrolled asthma, as determined by pulmonary function testing and effects on asthma control.

All patients were required to be symptomatic at screening despite being on treatment with medium or high stable doses of LABA/ICS. Approximately 3,092 male and female adult patients with asthma were randomized 1:1:1:1:1 (approximately 618 patients in each of the treatment groups) to receive either:

- IND/GLY/MF 150/50/80 µg (once-daily)
- IND/GLY/MF 150/50/160 µg (once-daily)
- IND/MF 150/160 µg (once-daily)
- IND/MF 150/320 µg (once-daily)
- Sal/Flu 50/500 µg (twice-daily, via Accuhaler<sup>®</sup>)

The primary objective of this study was to demonstrate superiority of both high-dose IND/GLY/MF versus high-dose IND/MF and medium-dose IND/GLY/MF versus medium-dose IND/MF, all delivered once-daily, in improving trough FEV<sub>1</sub> (volume of air that can be forced out in the first second of expiration approximately 24 hours post-administration of study drug) after 26 weeks of treatment in patients with asthma.

The key secondary objective was to demonstrate the superiority of both doses of IND/GLY/MF versus respective doses of IND/MF, in improving Asthma Control Questionnaire (ACQ-7) score after 26 weeks of treatment in patients with asthma.

Other secondary analyses also included reduction of exacerbation rate, comparing high-dose IND/GLY/MF with high-dose IND/MF and medium-dose IND/GLY/MF with medium-dose IND/MF. Secondary analyses included efficacy comparisons for both doses of IND/GLY/MF compared with Sal/Flu (50/500 µg).

The study showed that IND/GLY/MF was superior to IND/MF in improving trough FEV<sub>1</sub> after 26 weeks, meeting the primary endpoint. The key secondary endpoint, improvement in ACQ-7 score for IND/GLY/MF versus IND/MF was not met but tested treatments showed clinically meaningful improvements in this measure of symptoms from baseline at Week 26. Among other secondary analyses, a substantial reduction was observed in moderate-to-severe and severe asthma exacerbation rates with IND/GLY/MF compared with twice-daily Sal/Flu (50/500 µg).

IND/GLY/MF was generally well tolerated, and safety was comparable across treatment arms.

Full information on all of the endpoints measured in the study can be accessed at [ClinicalTrials.gov](https://clinicaltrials.gov) (Identifier: NCT02571777).

#### **About the PALLADIUM study<sup>13</sup>**

PALLADIUM (NCT02554786) was a multicenter, randomized, 52-week treatment, double-blind, triple-dummy, parallel-group study, designed to assess the efficacy and safety of IND/MF compared with MF alone in patients with asthma.

PALLADIUM included 2,216 male and female patients (including 107 adolescents, aged ≥12 to <18 years old) with medium or high-dose ICS or low-dose ICS/LABA use 3 months prior to screening, a pre-bronchodilator FEV<sub>1</sub> of ≥50% and less than 80% of the predicted normal value for the patient and an Asthma Control Questionnaire (ACQ-7) score of greater than 1.5.

Patients were randomized 1:1:1:1:1 to receive either high-dose IND/MF (150/320 µg) once-daily delivered via Breezhaler<sup>®</sup> (n=445); medium-dose IND/MF (150/160 µg) once-daily delivered via Breezhaler<sup>®</sup> (n=439); MF 400 µg once-daily delivered via Twisthaler<sup>®</sup> (n=444); MF 800 µg administered as 400 µg twice-daily delivered via Twisthaler<sup>®</sup> (n=442); or salmeterol xinafoate/fluticasone propionate (Sal/Flu) 50/500 µg twice-daily delivered via Accuhaler<sup>®</sup> (n=446).

The study showed that medium and high doses of IND/MF demonstrated significant improvements compared with MF in trough FEV<sub>1</sub> at Week 26 (Medium: 0.211 L; p<0.001) (High: 0.132 L; p<0.001). The key secondary endpoint of improvement in ACQ-7 at Week 26 was also met for combined doses of IND/MF compared with combined doses of MF (-0.209; p<0.001). These positive results were also observed at Week 52.

Analyses of other lung function endpoints showed greater improvements for IND/MF compared with MF in both morning and evening Peak Expiratory Flow (PEF). Reductions in daily rescue medication use and exacerbation rates were also observed. Patients demonstrated a 12% increase in FEV<sub>1</sub> and 200 mL within 30 minutes following administration of 400 µg salbutamol/360 µg albuterol (or equivalent dose) at the first visit or from historical data.

In the secondary analyses of comparison to Sal/Flu, high-dose IND/MF showed improvements in trough FEV<sub>1</sub> (0.048 L; p=0.040) at 52 weeks. In asthma control, high-dose IND/MF and Sal/Flu were comparable with a difference in ACQ-7 score of 0.010 (p=0.824). Improvements were observed in both morning and evening PEF (Morning: 13.8 L/min; p<0.001) (Evening: 9.1 L/min; p=0.002), and percentage of rescue medication free days over 52 weeks (4.3; p=0.034) in patients treated with high-dose IND/MF versus Sal/Flu. High-dose IND/MF also showed faster onset of action over Sal/Flu as demonstrated by FEV<sub>1</sub> measurement at 5 minutes on Day 1 (0.055 L; p<0.001).

IND/MF was generally well tolerated, and safety was comparable across treatment arms.

#### **About the QUARTZ study<sup>14</sup>**

The QUARTZ Study (NCT02892344) was a Phase III, multicenter, randomized, 12-week treatment, double-blind study, designed to assess the efficacy and safety of IND/MF (150/80µg) compared with MF (200 µg) delivered via the Twisthaler<sup>®</sup> device in adult and adolescent patients with asthma.

All patients were required to be on a stable low dose of ICS (with or without LABA) for at least one month prior to entering the run-in period. During the run-in period, all patients received open-label fluticasone propionate 100 µg twice-daily delivered via Accuhaler<sup>®</sup>. Patients meeting the eligibility criteria at the end of the run-in period were equally randomized (1:1) to one of the two treatment groups IND/MF 150/80 µg once-daily delivered via the dose-confirming Breezhaler<sup>®</sup> device, or MF 200 µg once-daily, delivered via Twisthaler<sup>®</sup>.

802 male and female patients (including 64 adolescents, aged ≥ 12 to < 18 years old) were randomized to receive IND/MF (n=398) or MF (n=404). The mean age was 45.6 years with a mean asthma duration of 14.0 years.

Mean pre-bronchodilator FEV<sub>1</sub> (% predicted of normal) was 75.1% at baseline and the mean FEV<sub>1</sub> reversibility after inhalation of short acting beta agonist was 20.7%. The majority of patients were treated with low-dose ICS (42.9%) or low-dose LABA/ICS (56.0%) prior to the study.

Spirometry was performed at the end of the treatment period. The primary objective was to demonstrate the superiority of IND/MF 150/80 µg once-daily (in the evening) compared with MF 200 µg once-daily in terms of trough FEV<sub>1</sub> after 12 weeks of treatment in adults and adolescents. The key secondary objective was to demonstrate the superiority of IND/MF 150/80 µg to MF 200 µg (once-daily) in terms of Asthma Control Questionnaire (ACQ-7) after 12 weeks of treatment.

IND/MF demonstrated statistically significant improvements in trough FEV<sub>1</sub> compared with MF after 12 weeks of treatment in adult and adolescent patients with inadequately controlled asthma (least squares [LS] mean treatment difference: 0.182 L, 95% CI: 0.148, 0.217; p<0.001). In addition, clinically meaningful lung function benefit for IND/MF was supported by improvements in evening PEF of 26.1 L/min compared with MF alone (95% CI, 21.0, 31.2).

IND/MF also demonstrated statistically significant improvements in asthma control compared with MF, as measured by ACQ-7 after 12 weeks of treatment (LS mean treatment difference: -0.218, 95% CI: -0.293, -0.143; p<0.001). In addition, a clinically meaningful improvement in ACQ-7 was supported by a responder analysis, in which the IND/MF group had a greater proportion of responders (improvement in ACQ-7 ≥=0.5) compared with the MF group (74.7% vs 64.9%, respectively (odd ratio: 1.69, 95% CI: 1.23, 2.33).

IND/MF was generally well tolerated, and safety was comparable across treatment arms.

#### **About the ARGON study<sup>15</sup>**

ARGON (NCT03158311) is a Phase IIIb, multicenter, randomized, 24-week, parallel-group, non-inferiority, open-label (blinded for the two IND/GLY/MF tested strengths), active-controlled study comparing the efficacy and safety of IND/GLY/MF with a free combination of salmeterol

xinafoate/fluticasone propionate (Sal/Flu) plus tiotropium in patients with uncontrolled asthma. The ARGON study has completed in the field and its Clinical Study Report is currently being finalized.

The purpose of this trial was to demonstrate that the efficacy of two strengths of the fixed-dose combination product IND/GLY/MF (High: 150/50/160 µg and Medium: 150/50/80 µg) is non-inferior to the efficacy of the free combination of Sal/Flu (50/500 µg) plus tiotropium (5 µg) in patients with uncontrolled asthma.

All patients were symptomatic at screening despite treatment with medium or high stable doses of LABA/ICS as defined by Asthma Control Questionnaire (ACQ-7) score  $\geq$  1.5.

Approximately 1,251 male and female patients with uncontrolled asthma (aged 18 and above) were randomized 1:1:1 (approximately 417 patients in each of the treatment groups) to receive either:

- IND/GLY/MF 150/50/80 µg (once-daily)
- IND/GLY/MF 150/50/160 µg (once-daily)
- Open label Sal/Flu 50/500 µg (twice-daily) delivered via Diskus® plus tiotropium delivered via Respimat®

The primary objective of this study was to demonstrate non-inferiority of both high-dose IND/GLY/MF and low-dose IND/GLY/MF to comparator Sal/Flu plus tiotropium after 24 weeks of treatment based on Asthma Quality of Life Questionnaire.

Secondary objectives included:

- To evaluate efficacy of high-dose IND/GLY/MF and medium-dose IND/GLY/MF compared with Sal/Flu plus tiotropium based on trough FEV<sub>1</sub> after 24 weeks of treatment
- To evaluate efficacy of high-dose IND/GLY/MF and medium-dose IND/GLY/MF compared with Sal/Flu plus tiotropium based on Asthma Quality of Life Questionnaire over 24 weeks of treatment.
- To evaluate efficacy of high-dose IND/GLY/MF and medium-dose IND/GLY/MF compared with Sal/Flu plus tiotropium based on ACQ-7 over 24 weeks of treatment.
- To evaluate efficacy of high-dose IND/GLY/MF and medium-dose IND/GLY/MF compared with Sal/Flu plus tiotropium based on lung function over 24 weeks of treatment.

### **Disclaimer**

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement

pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

### **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 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <https://twitter.com/novartisnews>  
For Novartis multimedia content, please visit <https://www.novartis.com/news/media-library>  
For questions about the site or required registration, please contact [media.relations@novartis.com](mailto:media.relations@novartis.com)

### **References**

- <sup>1</sup> Data on file
- <sup>2</sup> Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 23-26 March 2020 (updated) Share. Available at: <https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-23-26-march-2020-updated>. Last accessed April 2020
- <sup>3</sup> GBD Chronic Respiratory Disease Collaborators. Global, regional, and national deaths, prevalence, disability-adjusted life years, and years lived with disability for chronic obstructive pulmonary disease and asthma. 2017. Available at: [https://doi.org/10.1016/S2213-2600\(17\)30293-X](https://doi.org/10.1016/S2213-2600(17)30293-X)
- <sup>4</sup> AAFA. My Life With Asthma Survey Findings Report. Available at: <https://www.aafa.org/media/1684/my-life-with-asthma-in-2017-survey-findings-report.pdf>. Accessed April 2020.
- <sup>5</sup> Chung KF et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J* 2014;43(2):343-73.
- <sup>6</sup> Fang J et al. Demographic, clinical characteristics and control status of pediatric, adolescent, and adult asthma patients by GINA Step in a US longitudinal cohort. *Am J Resp Crit Care Med* 2018;197:A1903
- <sup>7</sup> Peters SP et al. Uncontrolled asthma: a review of the prevalence, disease burden and options for treatment. *Respir Med* 2006;100(7):1139-1151.
- <sup>8</sup> Katsaounou P et al. Still Fighting for Breath: a patient survey of the challenges and impact of severe asthma. *ERJ Open Res* 2018;4(4):00076-2018.
- <sup>9</sup> Price D et al. Asthma control and management in 8,000 European patients: the REcognise Asthma and Link to Symptoms and Experience (REALISE) survey. *NPJ Prim Care Respir Med* 2014;24:14009.
- <sup>10</sup> Price D, et al. Adverse outcomes from initiation of systemic corticosteroids for asthma: long-term observational study. *J Asthma Allergy* 2018;11:193-204.
- <sup>11</sup> Albers FC et al. Biologic treatment eligibility for real-world patients with severe asthma: The IDEAL study. *J Asthma* 2018;55(2):152-160.
- <sup>12</sup> ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT02571777>. Last accessed April 2020.
- <sup>13</sup> ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT02554786>. Last accessed April 2020.
- <sup>14</sup> ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT02892344>. Last accessed April 2020.
- <sup>15</sup> ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT03158311>. Last accessed April 2020.

###

### **Novartis Media Relations**

E-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

Peter Zuest  
Novartis Global External Communications  
+41 79 899 9812 (mobile)  
[peter.zuest@novartis.com](mailto:peter.zuest@novartis.com)

Phil McNamara  
Global Head, Respiratory Communications  
+41 79 510 8756 (mobile)  
[philip.mcnamara@novartis.com](mailto:philip.mcnamara@novartis.com)

**Novartis Investor Relations**

Central investor relations line: +41 61 324 7944

E-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Central

Samir Shah +41 61 324 7944

Pierre-Michel Bringer +41 61 324 1065

Thomas Hungerbuehler +41 61 324 8425

Isabella Zinck +41 61 324 7188

North America

Sloan Simpson +1 862 778 5052

Cory Twining +1 862 778 3258