

## MEDIA UPDATE

### **Novartis presents new findings at ERS reinforcing the efficacy of Enerzair<sup>®</sup> Breezhaler<sup>®</sup>, highlighting its digital companion, as well as showcasing commitment to low carbon footprint asthma solutions**

- *Novartis will present 12 abstracts at the European Respiratory Society (ERS) International Congress 2021 for Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (IND/GLY/MF\*) and Ateectura<sup>®</sup> Breezhaler<sup>®</sup> (IND/MF\*\*) — for patients whose asthma is uncontrolled with LABA/ICS<sup>^</sup> and ICS, respectively<sup>1,2</sup>*
- *Data from post hoc analyses of the Phase III PLATINUM program (including IRIDIUM and ARGON studies) further establish efficacy of Enerzair Breezhaler<sup>3-5</sup>*
- *Interim analysis of patient engagement and adherence assessment indicates ability of Enerzair Breezhaler optional digital companion (sensor and app) in supporting patient engagement and treatment adherence<sup>6</sup>*
- *New data explore the carbon footprint of Enerzair Breezhaler use — a dry powder inhaler — in keeping with the Novartis commitment to reduce the environmental impact of its asthma treatments<sup>7</sup>*

**Basel, September 3, 2021** — Novartis today announced 12 Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) and Ateectura<sup>®</sup> Breezhaler<sup>®</sup> [indacaterol acetate and mometasone furoate [IND/MF] abstracts to be presented at the upcoming European Respiratory Society (ERS) International Congress 2021, taking place virtually from September 5 – September 8, 2021. The data further establish the efficacy of Enerzair Breezhaler and will be unveiled alongside an interim analysis highlighting patient engagement and adherence levels with Enerzair Breezhaler's optional digital companion (sensor and app)<sup>3-6</sup>. In keeping with the Novartis commitment to reduce the environmental impact of its asthma combinations, Novartis will also share new data exploring the carbon footprint of Enerzair Breezhaler use<sup>7</sup>.

“Our presence at ERS this year reiterates our commitment to patients through the further development of first-in-class therapies like Enerzair Breezhaler, as well as by exploring the potential of digital health companions and the carbon footprint of our solutions,” said Dominic Brittain, Respiratory Global Program Head, Novartis Pharmaceuticals. “As a global leader in respiratory and allergy, we remain committed to reimagining medicine for patients living with chronic respiratory diseases like asthma.”

## Highlights of Enerzair Breezhaler data at the ERS Congress 2021 include:

New post hoc analysis results from the Phase III IRIDIUM study that suggests that using Enerzair Breezhaler as a step-up therapy from medium-dose LABA/ICS provides benefit beyond increasing ICS dose alone<sup>4</sup>.

- Efficacy of mometasone/indacaterol/glycopyrronium (MF/IND/GLY) on lung function and exacerbations in patients with inadequately controlled asthma with medium-dose ICS/LABA therapy (on GINA step 4) prior to study entry: Results from IRIDIUM study. H.A. Kerstjens et al.  
Details: Poster

New post hoc analysis from the Phase III PLATINUM program in which Ateectura Breezhaler and Enerzair Breezhaler showed clinical benefit compared to two widely used therapies<sup>3</sup>.

- Mometasone/indacaterol (MF/IND) and mometasone/indacaterol/glycopyrronium (MF/IND/GLY) versus fluticasone/salmeterol (FLU/SAL) and FLU/SAL+tiotropium (TIO) in patients with inadequately controlled asthma: data from the PLATINUM program. R. Van Zyl-Smit et al.  
Details: Poster

New post hoc analysis from the Phase III IRIDIUM study showed how each of the three components in Enerzair Breezhaler contribute to the substantial (36-42%) reduction in exacerbations seen versus twice daily high-dose SAL/FLU<sup>5</sup>.

- Evaluating contributions of mometasone (MF), indacaterol (IND) and glycopyrronium (GLY) to reduction of exacerbations in patients with inadequately controlled asthma: Results from the IRIDIUM study. K. R. Chapman et al.  
Details: Oral Presentation, 6 September, 9:30-11:00 CEST

An interim analysis of patient engagement and adherence assessment in Germany indicates patients with asthma using once daily Enerzair Breezhaler and digital companion (sensor and app) had a 72% engagement rate at baseline and maintained an 82% medication adherence rate over three months of treatment<sup>6</sup>.

- Assessment of patient engagement and adherence with once-daily indacaterol/glycopyrronium/mometasone (IND/GLY/MF) Breezhaler digital companion in asthma: interim analysis from Germany. H. Woehrle et al.  
Details: Oral Presentation, 7 September, 14:45-16:15 CEST

Data suggesting that the treatment of severe asthma exacerbations may have a negative environmental impact due to ambulance trips, emergency room visits and hospitalizations: the carbon footprint of a single severe asthma exacerbation could be equivalent to the use of a dry powder inhaler (Breezhaler<sup>®</sup>) for approximately 74 years<sup>7</sup>.

- Carbon footprint of severe asthma exacerbation management relative to Breezhaler dry powder inhaler. K.M. Beeh et al.  
Details: Oral Presentation, 5 September, 9:30-11:00 CEST

\*Indacaterol acetate (IND)/glycopyrronium bromide (GLY)/mometasone furoate (MF)

\*\*Indacaterol acetate (IND)/mometasone furoate (MF)

†Long-acting beta<sub>2</sub>-agonist (LABA)/long-acting muscarinic antagonist [LAMA]/inhaled corticosteroids (ICS)

^Long-acting beta<sub>2</sub>-agonist (LABA)/inhaled corticosteroids (ICS)

### **About Enerzair® Breezhaler® in the European Union (EU)**

On July 7, 2020, Novartis announced European Commission (EC) approval of Enerzair® Breezhaler® (IND/GLY/MF) 150/50/160 µg once-daily 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<sup>1</sup>. This formulation combines the bronchodilation of indacaterol acetate (a LABA) and glycopyrronium bromide (a long-acting muscarinic antagonist [LAMA]) with mometasone furoate (an ICS) in a precise once-daily formulation, delivered via the dose-confirming Breezhaler device. Enerzair Breezhaler is now also approved in multiple other jurisdictions in the high-dose (150/50/160µg) and medium-dose (150/50/80µg) formulations. GLY certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei Heptares and Vectura. MF is exclusively licensed to Novartis from a subsidiary of Merck & Co., Inc, Kenilworth, NJ, USA, for use in IND/GLY/MF (worldwide excluding the US).

IND/GLY/MF is administered via the dose-confirming Breezhaler device, which enables once-daily inhalation using a single inhaler. IND/GLY/MF is the first asthma treatment in the EU that can be prescribed together with an optional digital companion in select markets; the Propeller Health app and sensor custom-built for the Breezhaler device. The digital companion provides patients with inhalation confirmation, medication reminders and access to objective data that can be shared with their physician in order to support therapeutic decisions. The sensor for the Breezhaler device was developed by Propeller Health and is a CE marked medical device, designed and licensed to Novartis for use with the Breezhaler 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 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.

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

### **About Ateectura® Breezhaler® in the EU**

On May 30, 2020, Ateectura® Breezhaler® (IND/MF) 150/80 µg, 150/160 µg and 150/320 µg once daily received European Commission (EC) approval 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<sub>2</sub>-agonists<sup>7</sup>. 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 device. Mometasone furoate is exclusively licensed to Novartis from a subsidiary of Merck & Co., Inc, Kenilworth, NJ, USA, for use in IND/MF.

### **Disclaimer**

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### **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 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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### **References**

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2. Atecura® Breezhaler® (indacaterol acetate and mometasone furoate [IND/MF]) SmPC.
3. Van Zyl-Smit, R. *et al.* Mometasone/indacaterol (MF/IND) and mometasone/indacaterol/glycopyrronium (MF/IND/GLY) versus fluticasone/salmeterol (FLU/SAL) and FLU/SAL+tiotropium (TIO) in patients with inadequately controlled asthma: data from the PLATINUM program. Poster 2021 ERS.
4. Kerstjens, H.A. *et al.* Efficacy of mometasone/indacaterol/glycopyrronium (MF/IND/GLY) on lung function and exacerbations in patients with inadequately controlled asthma with medium-dose ICS/LABA therapy (on GINA step 4) prior to study entry: Results from IRIDIUM study. Poster 2021 ERS.
5. Chapman, Kenneth R. *et al.* Evaluating contributions of mometasone (MF), indacaterol (IND) and glycopyrronium (GLY) to reduction of exacerbations in patients with inadequately controlled asthma: Results from the IRIDIUM study. Oral Presentation, ERS 2021, 7 September, 14:45-16:15.
6. Woehrlé, H. *et al.* Assessment of patient engagement and adherence with once-daily indacaterol/glycopyrronium/mometasone (IND/GLY/MF) Breezhaler digital companion in asthma: interim analysis from Germany. Oral Presentation, ERS 2021, 7 September, 14:45-16:15.
7. Beeh, K.M. *et al.* Carbon footprint of severe asthma exacerbation management relative to Breezhaler dry powder inhaler. Oral Presentation, ERS 2021, 5 September, 09:30-11:00.

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