Novartis’ Ultibro® Breezhaler® significantly improved COPD patients’ lung function after direct switch from Seretide®

- New data showed switching moderate-to-severe, symptomatic COPD patients from Seretide® to Ultibro® Breezhaler® improved lung function and was well tolerated.

- The FLASH study is the first randomized controlled trial to investigate the direct switch of patients from steroid-containing Seretide to the dual bronchodilator Ultibro Breezhaler.

- Data presented at the Asian Pacific Society of Respirology (APSR) Congress in Sydney, Australia.

Basel, November 27, 2017 – Novartis today announced positive results from the FLASH† study examining the safety and efficacy of directly switching chronic obstructive pulmonary disease (COPD) patients from Seretide® (salmeterol/fluticasone) 50/500 mcg to Ultibro® Breezhaler® (indacaterol/glycopyrronium) 110/50 mcg†. The study met the primary endpoint demonstrating that switching patients to Ultibro Breezhaler resulted in significantly improved lung function (trough FEV₁)†.

The superiority of once-daily Ultibro Breezhaler over twice-daily salmeterol/fluticasone in improving lung function2-3 and reducing the rate of COPD exacerbations4 has been established in previous studies. The FLASH study is the first randomized controlled trial to confirm the benefits of directly switching patients from this steroid-containing therapy to the dual bronchodilator1, therefore avoiding the side effects of the long-term use of inhaled corticosteroids. Importantly, patients were switched without a wash-out period5 to mimic clinical practice1.

“It has already been established that Ultibro Breezhaler improves patients’ lung function when directly compared to Seretide in clinical trials,” said Shreeram Aradhye, Chief Medical Officer and Global Head of Medical Affairs for Novartis Pharmaceuticals. “This new research is important because it shows that this benefit also exists when directly switching patients from Seretide to Ultibro Breezhaler as would happen in everyday clinical practice. The FLASH study provides further evidence that it is possible to reduce the burden of long-term inhaled steroids in many COPD patients, as recommended by global treatment guidelines".

These results further reinforce the latest GOLD recommendations, which support the use of dual bronchodilation for the majority of symptomatic COPD patients and limit the use of steroid-containing therapies to specific patient types5.

Importantly, the data released today also indicated that the safety and tolerability profiles of the two treatments were similar1.

The FLASH study results were presented at the Asian Pacific Society of Respirology (APSR) Congress in Sydney, Australia (23-26 November 2017).
About the FLASH study
The FLASH study is a randomized, multicenter, double-blind, double-dummy, parallel-group, 12-week treatment trial. It involved a total of 502 moderate-to-severe symptomatically and non-frequently exacerbating chronic obstructive pulmonary disease (COPD) patients.

The primary objective of the study was to demonstrate the superiority of once-daily Ultibro® Breezhaler® 110/50 mcg compared with twice-daily salmeterol/fluticasone (50/500 mcg) in terms of improving lung function (trough pre-dose FEV₁ at Week 12).

Secondary objectives of the study were to investigate the effect of Ultibro Breezhaler compared with salmeterol/fluticasone on:
- Transition Dyspnea Index (TDI) focal score at Week 12
- Trough pre-dose forced expiratory vital capacity (FVC) at Week 12
- COPD symptoms at Week 12 as measured by the COPD Assessment Test (CAT)
- Mean rescue medication use (puffs/day) and percentage of days without rescue medication use over 12 weeks

The study also assessed the safety and tolerability over 12 weeks (including adverse events, serious adverse events and COPD exacerbations).

About Ultibro Breezhaler
Ultibro® Breezhaler® 110/50 mcg is a once-daily LABA/LAMA dual bronchodilator approved in the European Union (EU) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. Clinical trials have shown that it offers statistically significant improvements in bronchodilation compared to treatments widely used as current standards of care, including salmeterol/fluticasone 50/500 mcg and open-label tiotropium (18 mcg). Ultibro Breezhaler is currently approved for use in over 90 countries worldwide, including countries within the EU and Latin America, Japan, Canada, Switzerland and Australia.

About the Novartis COPD portfolio
Novartis is committed to addressing the unmet medical needs of COPD patients and improving their quality of life by providing innovative medicines and devices. The Novartis COPD portfolio includes Ultibro® Breezhaler® (indacaterol/glycopyrronium bromide), Seebri® Breezhaler® (glycopyrronium bromide) and Onbrez® Breéezhaler® (indacaterol), which are all indicated as maintenance treatments for COPD patients. Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura.

Novartis continues development of respiratory products for delivery via the low resistance Breezhaler inhalation device, which makes it suitable for patients with different severities of airflow limitation. The Breezhaler device allows patients to hear, feel and see that they have taken the full dose correctly.

About COPD
Chronic obstructive pulmonary disease (COPD) affects an estimated 210 million people worldwide and is the fourth leading cause of death. It is progressive (usually gets worse over time) and can be a life-threatening disease. COPD makes it difficult to breathe, with symptoms that have a destructive impact on patients’ function (i.e. activity limitation, decreased mobility) and quality of life.

Disclaimer
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generally be identified by words such as “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward healthcare cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues, 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 provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 121,000 full-time equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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* Seretide is a registered trademark of the GlaxoSmithKline Group of Companies
† Assessment of switching salmeterol/Fluticasone to indacateroL/glycopyrronium in A Symptomatic COPD patient cohort
‡ Unlike most clinical trials, Ultibro Breezhaler was started immediately after stopping salmeterol/fluticasone, to mimic clinical practice
** Patients with a history of up to one exacerbation in the past year
†† A long-acting beta2-adrenergic agonist
‡‡ A long-acting muscarinic antagonist

References


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9. Vogelmeier C, et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS 2013 abstract 851176; Session 82; Date: September 8, 2013 Time: 12:50-14:40].

10. Banerji D, et al. Dual bronchodilatation with once-daily QVA149 improves dyspnea and health status and reduces symptoms and rescue medication use in patients with COPD: the IGNITE trials. [ERS 2013 abstract 851388; Session 346; Date: September 10, 2013 Time: 8:30-10:30].


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**Novartis Media Relations**

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Beyza Oezel
Novartis Global Respiratory Franchise
Patient Advocacy & Communications
+41 61 696 9503 (direct)
+41 79 720 4038 (mobile)
beyza.oezel@novartis.com

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**Novartis Investor Relations**

Central investor relations line: +41 61 324 7944

E-mail: 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
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417

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