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Novartis data at ERS 2014 show once-daily Ultibro® Breezhaler® is superior in reducing COPD flare ups compared to Seretide®*

- Once-daily Ultibro® Breezhaler® reduced exacerbations (flare ups) by 31% compared to twice-daily Seretide® Accuhaler®* in moderate-to-severe COPD patients

- LANTERN study further confirmed superiority of Ultibro Breezhaler in improving lung function compared to Seretide® in moderate-to-severe COPD patients

- First presentation of LANTERN trial at European Respiratory Society International Congress involving over 700 COPD patients

Basel, September 7, 2014 – Novartis today presented new data that demonstrated once-daily Ultibro® Breezhaler® (indacaterol/glycopyrronium bromide) was superior in reducing exacerbations (flare ups) and improving lung function compared to twice-daily Seretide® Accuhaler®* (salmeterol/fluticasone (SFC)), in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD). These findings from the head-to-head LANTERN study were presented for the first time at the European Respiratory Society (ERS) International Congress, September 6-10, in Munich, Germany.

The LANTERN study showed Ultibro Breezhaler significantly reduced the rate of moderate-to-severe exacerbations by 31% compared to SFC, in moderate-to-severe COPD patients with a history of one exacerbation or none in the previous year. In addition, Ultibro Breezhaler patients had significantly increased lung function (trough FEV₁ 0.075 L (p<0.001); AUC₀–₄h 0.122 L (p<0.001)), as compared to SFC after 26 weeks of treatment. The safety profile of Ultibro Breezhaler was comparable to SFC.

“These new results from LANTERN provide further evidence of the potential of Ultibro Breezhaler to deliver better exacerbation reduction and improvements in lung function, compared to the current standard of care,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals.

The new findings from LANTERN support the use of Ultibro Breezhaler as an alternative steroid-free treatment to SFC in moderate-to-severe COPD patients. This approach is consistent with the Global Initiative for Chronic Obstructive Lung Disease 2014 guidelines.

COPD symptoms can have a major negative impact on a patient’s ability to breathe and function, reducing their quality of life. Essential daily activities such as climbing stairs can become very difficult as the condition gradually worsens. There is a need for newer treatment options in COPD because many patients remain symptomatic despite medical therapy.

About LANTERN
LANTERN was a randomized, double-blind, parallel-group, 26-week study involving 744 patients and conducted at 56 sites across China, Argentina, Chile and Taiwan.
primary objective of the study was to demonstrate the non-inferiority of Ultibro Breezhaler 110/50 mcg to SFC 50/500 mcg in terms of lung function (trough FEV₁) after 26 weeks of treatment in stable patients with moderate-to-severe COPD, with a history of one exacerbation or none in the previous year¹. Ultibro Breezhaler demonstrated non-inferiority and additionally showed superior efficacy versus SFC for the primary objective. In this study, exacerbations were a pre-specified exploratory endpoint.

**About Ultibro Breezhaler**

Ultibro Breezhaler is a once-daily dual bronchodilator approved in the European Union (EU) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD². Clinical trials have shown that it offers statistically significant improvements in bronchodilation compared to treatments widely used as current standards of care, including SFC 50/500 mcg⁵⁻¹⁰ and open-label tiotropium (18 mcg). Ultibro Breezhaler is currently approved for use in over 40 countries, including countries within the EU, Japan, Canada, countries within Latin America 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® Breezhaler®/Arcapta™ Neohaler™ (indacaterol), which are all indicated as maintenance treatments for COPD patients. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei.

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 limitation¹¹. The Breezhaler device allows patients to hear, feel and see that they have taken the full dose correctly²⁻¹¹.

**About COPD**

COPD affects an estimated 210 million people worldwide¹² and is projected to be the third leading cause of death by 2020³. It is progressive (usually gets worse over time), and can be a life-threatening disease³,¹². 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 life³,¹². It is often considered to be a disease of later years, but estimates suggest that 50% of those with COPD are now less than 65 years old, resulting in increases in absenteeism, premature retirement and reductions in workforce participation¹³,¹⁴.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as “potential,” “support,” “can,” “offers,” “committed,” “continues,” “projected,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Ultibro Breezhaler, or regarding potential future revenues from any or all of the products in the Novartis COPD portfolio, including Ultibro Breezhaler. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Ultibro Breezhaler will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that any of the products in the Novartis COPD portfolio will receive additional regulatory approvals or be commercially successful in the future. In particular, management’s expectations regarding these products could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data;
unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected 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, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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*The LANTERN study used Seretide® (salmeterol/fluticasone) 50/500 mcg, which is indicated in the UK for the symptomatic treatment of patients with COPD, with a FEV₁ <60% predicted normal (prebronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. The patient population in the LANTERN study were stable moderate-to-severe COPD patients with a history of one exacerbation or none in the previous year. Seretide® is also known as Advair®, and Accuhaler® is also known as Diskus®. Seretide®, Advair®, Diskus® and Accuhaler® are registered trademarks of the GlaxoSmithKline group of companies.

References
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