Novartis once-daily Ultibro® Breezhaler® showed superior efficacy versus Seretide® for COPD patients in second head-to-head study

- Ultibro® Breezhaler® demonstrated superiority in lung function compared to Seretide® Accuhaler® in chronic obstructive pulmonary disease (COPD) patients with or without exacerbations in the previous year

- Primary and key secondary objectives met in pivotal Phase III LANTERN study

- Positive results to be part of the regulatory submission for Ultibro Breezhaler in China later this year

Basel, April 30, 2014 – Novartis today announced positive first results from the Phase III head-to-head LANTERN study, which showed the superiority of once-daily Ultibro® Breezhaler® (indacaterol/glycopyrronium) 110/50 mcg in improving lung function compared to twice-daily Seretide® Accuhaler® (salmeterol/fluticasone (SFC)) 50/500 mcg in COPD patients with or without a history of moderate-to-severe exacerbations in the previous year. Ultibro Breezhaler met both the primary and key secondary objectives.

The primary objective of the LANTERN study was to demonstrate the non-inferiority of Ultibro Breezhaler to SFC in terms of lung function (trough FEV₁) after 26 weeks of treatment in patients with moderate-to-severe COPD, with or without a history of moderate-to-severe exacerbations in the previous year. Ultibro Breezhaler demonstrated non-inferiority and additionally showed superior efficacy versus SFC for the primary objective. These results will be part of the regulatory submission of Ultibro Breezhaler in China later this year.

“This is the second time Ultibro Breezhaler has shown superiority in improving lung function to Seretide® in a head-to-head study and confirms benefits beyond this current standard of care,” said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. “Such promising data will be part of a regulatory submission in China later this year and is exciting news for the COPD community and ultimately patients.”

The LANTERN study also showed superiority of Ultibro Breezhaler compared to SFC for the key secondary objective of lung function (FEV₁ AUC₀–₄h) over the first four hours post dose at week 26. The safety and tolerability profile of Ultibro Breezhaler was comparable to SFC.

COPD is a major public health concern in China, ranking first in terms of the country’s disease burden¹. Recent estimates suggest that in China over 40 million people have COPD² and the overall prevalence in people aged 40 years or older is 8%¹. COPD symptoms can have a major, negative impact on a patient’s ability to breathe and function and they reduce their quality of life³. Essential daily activities such as climbing stairs can become very difficult as the condition gradually worsens⁴. There is a need for new treatment options in COPD because many patients remain symptomatic despite medical therapy⁵.
About LANTERN
LANTERN was a randomized, double-blind, parallel-group, 26-week study conducted at 56 sites across China, Argentina, Chile and Taiwan. The study randomized 741 patients to assess the efficacy and safety of Ultibro Breezhaler (indacaterol/glycopyrronium) 110/50 mcg compared to SFC 50/500 mcg in patients with moderate-to-severe COPD, with or without exacerbations in the previous year.

ILLUMINATE was the first study to demonstrate that Ultibro Breezhaler achieved superior lung function in patients with moderate-to-severe COPD and no history of exacerbations in the previous year, compared with twice-daily salmeterol/fluticasone 50/500 mcg administered with the Accuhaler® dry powder inhaler.

About Ultibro® Breezhaler®
Ultibro Breezhaler (indacaterol/glycopyrronium bromide) is a novel, once-daily dual bronchodilator approved in the EU as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. Clinical trials have shown that Ultibro Breezhaler offers statistically significant improvements in bronchodilation compared to treatments widely used as current standards of care, including SFC 50/500 mcg, in patients with no history of moderate or severe exacerbations over the last year and open-label tiotropium (18 mcg). Ultibro Breezhaler is currently approved for use in over 30 countries, including the EU, Japan, Canada 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 Onbrez® Breezhaler®/Arcapta™ Neohaler™ (indacaterol), Seebri® Breezhaler® (glycopyrronium bromide) and Ultibro Breezhaler (indacaterol/glycopyrronium bromide), 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 limitation. The Breezhaler® device allows patients to hear, feel and see that they have taken the full dose correctly.

About COPD
COPD is a progressive life-threatening disease that 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. It affects an estimated 210 million people worldwide and is projected to be the third leading cause of death by 2020. COPD 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 participation.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “to be,” “later this year,” “will,” “can,” “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](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[15]. The patient population in the LANTERN study who received salmeterol/fluticasone administered via the Accuhaler® dry powder inhaler, were moderate-to-severe COPD patients with or without exacerbations 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

9. Vogelmeier C et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes versus placebo, indacaterol, glycopyrronium, tiotropium and salmeterol/fluticasone in patients with COPD. [ATS abstract 40759; Session C45; Date: May 21, 2013 Time: 8:15 -10:45].
10. Vogelmeier C et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS abstract 851178; Session 82; Date: September 8, 2013 Time: 12:50-14:40].

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


