Novartis' INSTEAD study for Onbrez® Breezhaler® in patients with moderate COPD meets primary objective

- Results confirm non-inferiority of Onbrez® Breezhaler® (indacaterol) in lung function compared to Seretide®* (salmeterol/fluticasone) in the studied population

- In INSTEAD study, patients with moderate COPD and no exacerbations in the past year were switched from salmeterol/fluticasone to Onbrez Breezhaler

- Study showed similar symptomatic benefits in terms of shortness of breath and health status in patients treated with Onbrez Breezhaler compared to those on salmeterol/fluticasone

Basel, April 25, 2014 – Novartis announced today top-line results from the Phase IV INSTEAD switch study in patients with chronic obstructive pulmonary disease (COPD), which met its primary objective. Once-daily Onbrez® Breezhaler® (indacaterol) 150 mcg demonstrated non-inferiority in lung function at week 12 to twice-daily Seretide®* (salmeterol/fluticasone propionate (SFC)) 50/500 mcg in patients with moderate COPD and no exacerbations in the previous year.

The INSTEAD switch study also showed similar symptomatic benefits in terms of shortness of breath and health status after 12 and 26 weeks in patients treated with Onbrez Breezhaler compared to those on SFC. The safety profile of Onbrez Breezhaler observed in this study was consistent with previously reported results from Phase III studies.

“These positive results help inform the switch from salmeterol/fluticasone to Onbrez Breezhaler in patients with moderate COPD and who are at low risk of exacerbations. This confirms that Onbrez Breezhaler provides an effective maintenance treatment option for these patients,” said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. “In addition, these results support international guidelines, which advise against the use of inhaled corticosteroids due to long-term risks in COPD patients at low risk of exacerbations.”

COPD affects an estimated 210 million people worldwide² and is projected to be the third leading cause of death by 2020¹. Treatments that effectively control the symptoms of COPD and allow patients to continue with their daily activities are very important in helping address the unmet needs in the management of COPD²,³,⁴.

INSTEAD was a global, randomized, double-blind, parallel-group, 26-week study. This study randomized 581 patients with moderate COPD who had been taking SFC* for at least three months to either continue on SFC* or switch to indacaterol. The primary objective of this study was to demonstrate the non-inferiority of indacaterol versus SFC* in lung function (trough FEV₁) after 12 weeks of treatment in patients with moderate COPD who had experienced no exacerbations in the previous year. Data from this study are expected to be presented at major medical congresses later this year.
About Onbrez Breezhaler

Onbrez Breezhaler® (indacaterol) is a once-daily inhaled long-acting beta_{2}-adrenergic agonist (LABA) that offers clinically relevant 24 hour bronchodilation combined with a rapid onset of action within five minutes at first dose, as demonstrated in the INERGIZE Phase III trial program\textsuperscript{5,18}. Onbrez Breezhaler 150 mcg provided greater clinical benefit in terms of reduced shortness of breath, lower use of rescue medication and improved health status, compared with blinded tiotropium 18 mcg\textsuperscript{16}. Onbrez Breezhaler was first approved and launched in the EU (150 mcg and 300 mcg once-daily doses) for maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD\textsuperscript{19}. It has now received approvals in more than 100 countries around the world and is available in Japan (as Onbrez Inhalation Capsules 150 mcg once-daily) and in the USA (as Arcapta\textsuperscript{TM} Neohaler\textsuperscript{TM} 75 mcg once-daily).

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\textsuperscript{®} Breezhaler\textsuperscript{®} / Arcapta\textsuperscript{®} Neohaler\textsuperscript{®} (indacaterol), Seebri\textsuperscript{®} Breezhaler\textsuperscript{®} (glycopyrronium bromide) and Ultibro\textsuperscript{®} Breezhaler\textsuperscript{®} (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\textsuperscript{®} inhalation device, which makes it suitable for patients with different severities of airflow limitation\textsuperscript{20}. The Breezhaler device allows patients to hear, feel and see that they have taken the full dose correctly\textsuperscript{19,20}.

About COPD

COPD is a progressive life-threatening disease that makes it hard to breathe, with symptoms that have a destructive impact on patients’ function and quality of life\textsuperscript{1,21}. 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\textsuperscript{3,4}.

*In some countries, Seretide\textsuperscript{®} (salmeterol/fluticasone) 50/500 mcg is indicated for the symptomatic treatment of patients with COPD, with a FEV\textsubscript{1} <60% predicted normal (prebronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. The patient population in the INSTEAD study who received salmeterol/fluticasone were moderate COPD patients who had not exacerbated twelve months prior to entry. The INSTEAD study used the Accuhaler® dry powder inhaler, also known as Diskus®. Seretide®, Diskus® and Accuhaler® are registered trademarks of the GlaxoSmithKline group of companies.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “projected,” “expected,” “later this year,” “committed,” “continues,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Onbrez Breezhaler, or regarding potential future revenues from any or all of the products in the Novartis COPD portfolio, including Onbrez 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 Onbrez 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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