Novartis commends publication of major report which recommends broad use of dual bronchodilators to treat COPD

- 2017 GOLD report recommends the first-line use of dual bronchodilators, such as Ultibro® Breezhaler®, in the treatment of the majority of symptomatic COPD patients

- Bronchodilation regarded as the foundation treatment for COPD patients prior to the use of inhaled steroid-containing therapies, as supported by Novartis’ FLAME study evidence

- Today’s recommendations expected to translate to health care professionals moving away from the historical reliance on inhaled corticosteroid combinations for the treatment of COPD

Basel, November 21, 2016 – Novartis welcomes the publication of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017 report. For the first time, GOLD has recommended the first-line use of dual bronchodilators, such as Ultibro® Breezhaler® (indacaterol/glycopyrronium bromide) 110/50 mcg, in the treatment of the majority of symptomatic chronic obstructive pulmonary disease (COPD) patients, regardless of their exacerbation risk.

The GOLD 2017 report is a tool to help health care professionals worldwide implement effective COPD management programs. Significantly, the use of inhaled steroid-containing combination therapies is now only recommended in a minority of patients (those with a history of two or more exacerbations in the previous year, or one hospitalization), following dual bronchodilator (LABA/LAMA*) treatment.

“Today’s publication of the new GOLD 2017 report is a major step in the fight to help improve the diagnosis and management of COPD around the world,” said Vasant Narasimhan, Global Head Drug Development and Chief Medical Officer for Novartis. “Reflecting the latest clinical evidence, the report not only supports bronchodilation as a first treatment step for the majority of COPD patients, but also recommends a more critical risk-based assessment of specific patient types that may benefit from inhaled steroid-containing therapies. We are pleased that the FLAME study helps underpin these important recommendations.”

Today’s new recommendations may translate to health care professionals moving away from the historical reliance on inhaled corticosteroid (ICS)/LABA combinations as first line therapy for the prevention of exacerbations. The GOLD 2017 report clearly identifies the elevated risk of adverse effects (including pneumonia) when using these treatments and references evidence showing no significant harm from withdrawing this medication in many patients when used as part of a triple regimen.

Ultibro Breezhaler is currently the only steroid-free treatment to offer prescribers clinically proven superiority over the most prescribed ICS/LABA combination** in preventing COPD exacerbations. The head-to-head FLAME study was considered significant enough to be
included as a reference for the first-line use of dual bronchodilators in symptomatic patients with high exacerbation risk.

**About GOLD**
The Global Initiative for Chronic Obstructive Lung Disease (GOLD) is an independent organization that was launched in 1997. It collaborates with health care professionals and public health officials worldwide to raise awareness of COPD and improve disease prevention and treatment.

Through the development of evidence-based strategy documents for COPD management, GOLD works to improve the lives of people with COPD in every corner of the globe.

**About Ultibro Breezhaler**
Ultibro Breezhaler (indacaterol/glycopyrronium bromide) 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 SFC 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® Breezhaler®/Arcapta™ Neohaler™ (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 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**
Chronic obstructive pulmonary disease (COPD) affects an estimated 210 million people worldwide and is the third 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**
The foregoing release contains forward-looking statements that can be identified by words such as “recommends,” “recommendations,” “expected,” “may,” “committed,” “continues,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Ultibro Breezhaler or the other products in the Novartis COPD Portfolio, or regarding potential future revenues from Ultibro Breezhaler and the other products in the Novartis COPD Portfolio. 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 or any
of the other products in the Novartis COPD Portfolio 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 Ultibro Breezhaler or any of the other products in the Novartis COPD Portfolio will be commercially successful in the future. In particular, management’s expectations regarding Ultibro Breezhaler and the other products in the Novartis COPD Portfolio 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 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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in approximately 180 countries around the world. For more information, please visit http://www.novartis.com.

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Notes
- Long-acting beta2-adrenergic agonist/Long-acting muscarinic antagonist
- ** Seretide® Accuhaler® (salmeterol/fluticasone) 50 microgram /500 microgram /dose inhalation powder. Seretide and Accuhaler are registered trademarks of the GlaxoSmithKline group of companies

References
5. 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].
6. Vogelmeier C, et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS 2013 abstract 85178; Session 82; Date: September 8, 2013 Time: 12:50-14:40].
7. 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 2013 abstract 851388; Session 346; Date: September 10, 2013 Time: 8:30-10:30].

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