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

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2017 GOLD report recommends the first-line use of dual bronchodilators, such as indacaterol/glycopyrronium bromide, 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 steroidcontaining therapies, as supported by Novartis' FLAME study evidence

GOLD 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 18, 2016 – Novartis welcomed 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 indacaterol/glycopyrronium bromide, 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 treatment, consisting of a long-acting beta2-adrenergic agonist and long-acting muscarinic antagonist (LABA/LAMA).

"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 Dr. Francis M. Domingo, Chief Scientific Officer, Novartis Healthcare Philippines. "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."

"The new GOLD recommendations may translate to health care professionals moving away from the historical reliance on inhaled corticosteroid [ICS] and 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," said Dr. Tim S. Trinidad, Chairman, Philippine College of Chest Physicians (PCCP) Council on COPD and Pulmonary Rehabilitation.

Indacaterol/glycopyrronium bromide 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 Indacaterol/glycopyrronium bromide

Indacaterol/glycopyrronium bromide 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). Indacaterol/glycopyrronium bromide 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 indacaterol/glycopyrronium bromide, glycopyrronium bromide and 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 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.

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 more than 180 countries around the world. For more information, please visit <u>http://www.novartis.com</u>.

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