

****PRESS RELEASE****

New study published in *The Lancet* shows Trimbow[®] superiority over Ultibro[®] Breezhaler[®]

- The TRIBUTE study showed superiority of Chiesi's triple extrafine formulation Trimbow[®] over Ultibro[®] Breezhaler[®] (indacaterol/glycopyrronium bromide) in terms of moderate to severe exacerbations, lung function and health-related quality of life in patients affected by Chronic Obstructive Pulmonary Disease (COPD)
- Chiesi's triple extrafine formulation significantly reduced the rate of moderate to severe exacerbation, compared to indacaterol/glycopyrronium bromide with a similar safety profile (including pneumonia).
- Results published in the Lancet may have important implications for the treatment of COPD patients

Parma, February 12, 2018 – Chiesi Group (Chiesi) today announced the **Lancet publication** of the **TRIBUTE study** comparing the efficacy of the **extrafine triple formulation Trimbow[®]** (beclometasone dipropionate/formoterol fumarate/glycopyrronium)* 87/5/9 mcg to Ultibro[®] Breezhaler[®] (indacaterol/glycopyrronium bromide [IGB])** 110/50 mcg, in reducing Chronic Obstructive Pulmonary Disease (COPD) moderate to severe exacerbations. In addition to meeting the primary endpoint (superiority), findings demonstrated the superiority of Chiesi's extrafine triple formulation over indacaterol/glycopyrronium bromide on lung function parameters and quality of life¹. The treatment with Chiesi's extrafine triple formulation showed similar safety profile compared with indacaterol/glycopyrronium bromide.

* an inhaled corticosteroid/ long-acting beta2-adrenergic agonist/muscarinic antagonist

** a long-acting beta2-adrenergic agonist/muscarinic antagonist

"This study helps to fill some of the evidence gaps in the management of COPD², by demonstrating the benefit of adding an ICS in patients who still report exacerbations despite dual bronchodilation. Exacerbations are an important outcome measure with relevant repercussions on the general well-being and overall status of COPD patients", said **Stefano Petruzzelli, Chief Medical Officer and Head of Global Clinical Development, Chiesi Group**. "The 2018 GOLD document³ considers COPD exacerbations as *important events in the management of COPD because they negatively impact health status, rates of hospitalization and readmission, and disease progression*. It is well established that COPD exacerbations *contribute to disease progression* and that *exacerbations can also cluster in time and once a COPD patient experiences an exacerbation, it will trigger increased susceptibility to another event*, further underlining the importance of their prevention. Exacerbations also accelerate the progressive decline in lung function in COPD patients and their frequency is now recognised as a key component of the characterisation of patients with COPD. Therefore, the prevention and treatment of COPD exacerbations (in particular moderate and severe exacerbations) has become a primary goal of health care providers^{4,5}. I believe that the TRIBUTE results may impact the future management and treatment of COPD patients."

TRIBUTE met the primary endpoint, with a significant 15% reduction in the rate of moderate-to-severe exacerbations with Trimbow[®] compared to IGB (which is an effective^{6,7} and widely used COPD treatment). In addition and to support the results on the primary endpoint, Trimbow[®] was superior to IGB in terms of lung function and health related quality of life outcomes (HRQoL- St. George Respiratory Questionnaire).

These data will also be presented at the 2018 Annual Meeting of the American Thoracic Society in San Diego, USA.



People and ideas for innovation in healthcare

About TRIBUTE

TRIBUTE was a randomised, parallel-group, double-blind, double-dummy, active controlled Phase 3b study, involving 1534 patients and conducted in 187 sites across 18 countries. This study was the first to compare specifically a fixed triple therapy with a fixed dual bronchodilator combination, both in a single inhaler, in terms of reducing moderate to severe exacerbations.

About Trimbow®

Trimbow® 87/5/9 mcg (pressurized metered dose inhaler) is a twice-daily ICS/LABA/LAMA triple fixed dose combination approved in the European Union (EU) as a “maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist.” (for effects on symptoms control and prevention of exacerbations see section 5.1.

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004257/WC500233163.pdf

About Chiesi Group

Headquartered in Parma, Italy Chiesi Group is an international research-focused Healthcare group, with over 80 years of experience in the pharmaceutical industry. Chiesi researches, develops and markets innovative drugs in the respiratory therapeutics, specialist medicine and rare diseases areas. Its R&D centres in Italy, France, USA, UK, Denmark and Sweden integrate their efforts to advance Chiesi's pre-clinical, clinical and registration programs. Chiesi employs over 5,000 people, 560 of whom are solely dedicated to Research and Development activities. www.chiesi.com.

References

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