****PRESS RELEASE****

Chiesi Group receives the European Marketing authorisation for the extrafine triple-combination therapy for the treatment of moderate to severe asthma

- It is the first extrafine fixed triple combination therapy in a single inhaler to be approved for use in moderate to severe asthma patients[1,2]. This follows the 2017 approval of this therapeutic option for the treatment of Chronic Obstructive Pulmonary Disease (COPD).
- The Marketing Authorization approval is based on CHMP positive opinion and European Commission approval on data obtained in 4 clinical studies involving close to 3000 patients.

Parma (Italy), February 1, 2021 – Chiesi an international research-focused Healthcare group (Chiesi Group), announces that the European Commission has granted the marketing authorisation for Chiesi extrafine triple therapy combination ICS/LABA/LAMA in a single inhaler, for the treatment of moderate to severe asthma. This follows the 2017 approval of this therapeutic option for the treatment of Chronic Obstructive Pulmonary Disease (COPD).[3]

The triple therapy is a combination of Inhaled Corticosteroid (ICS) / Long-acting β2-agonist (LABA)/long-acting muscarinic antagonist (LAMA) that contains Beclometasone dipropionate (BDP; inhaled corticosteroid) , Formoterol fumarate (FF; long-acting β2 agonist) and Glycopyrronium (G; long-acting muscarinic antagonist).[1] Chiesi triple therapy for asthma is the first and only extrafine triple combination able to reach and treat the whole bronchial tree including small airways where inflammation is located[4]. Chiesi's Modulite® extrafine particle technology allows more time for coordination of inhalation.[1,5]
The product is provided with a dose counter that allow patients to track and manage their treatment efficiently.

"This is the first step towards taking our industry-leading triple therapy for COPD patients and providing the same level of treatment for Asthma patients.," said ***Alessandro Chiesi, Chiesi Group Chief Commercial Officer.*** "Chiesi is committed to developing and delivering industry-first alternatives to aid patients in the management of their respiratory conditions and treatment. The European Commission' approval brings us one step closer to providing uncontrolled asthma patients with new and improved treatment options for their care, reducing exacerbations and simplifying the use for patients thanks to a single inhaler triple therapy".

Asthma is a chronic inflammatory disease affecting over 339 million people worldwide[9]. According to GINA Report, people with uncontrolled asthma have poor symptom control and/or frequent exacerbations requiring oral corticosteroids or experience serious exacerbations requiring hospitalisation[2].

In patients with uncontrolled asthma, Chiesi triple therapy has been shown to reduce exacerbations and improve lung function in comparison to ICS/LABA[1] (Inhaled Corticosteroid / Long-acting beta-agonist) and offers an alternative for patients with poor adherence on ICS/LABA, providing all day coverage to alleviate both day and night symptoms.[7]
The CHMP recommendation and the European Commission decision are based on the efficacy and safety data of 4 clinical studies involving close to 3000 patients.

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About Chiesi Group
Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused healthcare group with 85 years of experience in the pharmaceutical industry and a global presence in 29 countries. Chiesi researches, develops, and markets innovative drugs in the respiratory therapeutics, specialist medicine, and rare disease areas. Its R&D organization is headquartered in Parma (Italy), and is integrated with R&D groups in France, the USA, the UK and Sweden to advance Chiesi's pre-clinical, clinical and registration programs. Chiesi employs over 6,000 people. Chiesi Group is a certified Benefit corporation. For more information, please visit www.chiesi.com.

About Chiesi triple therapy
Chiesi triple therapy is the first extrafine fixed triple combination of Inhaled Corticosteroid (ICS) / Long-acting β2-agonist (LABA) / long-acting muscarinic antagonist (LAMA) that contains Beclometasone dipropionate (BDP), Formoterol fumarate (FF) and Glycopyrronium (G). Our fixed triple therapy will be available as twice a day pMDI (pressurized metered dose inhaler) to be licensed for maintenance treatment of moderate to severe asthma. Chiesi triple therapy is also approved in COPD as 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 or a combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist.

About Asthma

Asthma is a common long-term condition that can affect people of all ages and causes inflammation in the airways. The prevalence of asthma in the European Union (EU) is 8.2% in adults and 9.4% in children.[6] Difficult-to-treat, or severe asthma occurs in 24% of patients. The direct and indirect costs of asthma to societies are substantial. Recent calculations estimate direct costs within the EU to be nearly €20 billion, indirect costs to be €14 billion and a monetized value of DALYs lost to be €38 billion, which totals €72 billion.

References

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