PRESS RELEASE

# Chiesi Group receives European Marketing Authorization for Trimbow® inhalation powder (beclometasone dipropionate, formoterol fumarate dihydrate and glycopyrronium) delivered through NEXThaler, an extrafine formulation fixed triple combination therapy for the treatment of moderate to severe COPD

- *Chronic obstructive pulmonary disease (COPD) patients for whom a dry powder inhaler device is preferred, can now benefit from an extrafine formulation fixed triple combination therapy containing an inhaled corticosteroid (ICS) / long-acting β2-agonist (LABA) / long-acting muscarinic antagonist (LAMA) in a single device.*
- *With this new European authorization, Chiesi reinforces its commitment to providing a broad portfolio of formulations and devices to COPD patients.*

**Parma, Italy, April 21 2021** – Chiesi, an international research-focused healthcare group (Chiesi Group), today announced that the European Commission has granted the marketing authorization for Trimbow® inhalation powder delivered through NEXThaler (beclometasone dipropionate, formoterol fumarate dihydrate and glycopyrronium), an extrafine formulation triple fixed combination therapy in a single dry powder inhaler (DPI), for the 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.[1,2]

Chiesi's triple therapy in a pressurized metered dose inhaler (pMDI) formulation was previously approved in 2017[3] and with this new authorization, COPD patients for whom a DPI is preferred may now benefit from this therapeutic option in a NEXThaler device. It is extremely important to have both options available for different patients' needs as pMDIs and DPIs are the most commonly used devices for patients with chronic respiratory diseases such as COPD. Tailoring inhaler choice to a patient's ability to use specific devices, coupled with ongoing education to support optimal inhaler usage, may improve patient confidence and enhance both adherence and disease control.[4]

"With the marketing authorization for our triple therapy in a NEXThaler device in the EU, the Chiesi Group reinforces its commitment to providing a broad portfolio of formulations and devices to COPD patients and physicians." comments **Alessandro Chiesi**, Chief Commercial Officer, Chiesi Group. "Chiesi triple therapy is today the first and only triple fixed combination treatment providing both pMDI and DPI devices as options for patients and physicians. We aim to make this treatment available to appropriate patients in Europe as soon as possible."

Chiesi's triple therapy in a NEXThaler device was approved in EU based on the TRI-D study which found similar efficacy and safety to the pMDI formulation in patients with moderate to severe COPD.[5] Data from the TRILOGY, TRINITY and TRIBUTE clinical trials have already established that Chiesi's triple therapy in a pMDI formulation is an efficacious and well-tolerated treatment for moderate to severe COPD.[6,7,8]

The NEXThaler device is equipped with a counter for the inhalations. The number of inhalations shown in the window on the device does not decrease on closing the cover if the patient has not inhaled through the inhaler[2], which potentially helps them track and manage their treatment. NEXThaler is a device with a breath-activated mechanism (BAM) which allows the dose to be fully delivered when the optimal inspiratory flow rate is reached.[2]
For the EU Summary of Product Characteristics for Chiesi's triple therapy, please visit https://www.ema.europa.eu/en/documents/product-information/trimbow-epar-product-information_en.pdf.

###

About Chiesi Group
Based in Parma, Italy, Chiesi is an international research-focused pharmaceuticals and healthcare group with over 85 years' experience, operating in 30 countries with more than 6,000 employees (Chiesi Group). To achieve its mission of improving people's quality of life by acting responsibly towards society and the environment, the Group research, develops and markets innovative drugs in its three therapeutic areas: AIR (products and services that promote respiration, from new-born to adult populations), RARE (treatment for patients with rare and ultra-rare diseases) and

CARE (products and services that support special care and consumer-facing self-care). The Group's Research and Development center is based in Parma and works alongside 6 other important research and development centres in France, the U.S., Canada, China, the UK, and Sweden to promote its pre-clinical, clinical and regulatory programs. Chiesi, since 2019, is the world's largest Certified B Corporation™ pharmaceutical group. Chiesi Farmaceutici S.p.A. has changed in 2018 its legal status to a Benefit Corporation, by incorporating a double purpose for the creation of shared value, and to generate value for its business, for society and the environment. The global B Corporation movement promotes business as a force for good. Moreover, as a Benefit Corporation, Chiesi Farmaceutici S.p.A. is required by law to include objectives of common benefit in its bylaws and to report annually in a transparent way. The Group is committed to becoming carbon neutral by the end of 2035.
For further information: www.chiesi.com

## About Chiesi triple therapy[1]

Chiesi's triple therapy is an extrafine formulation, fixed triple combination, of beclometasone dipropionate (ICS) / formoterol fumarate (LABA) / glycopyrronium (LAMA). The therapy in pMDI and DPI device is licensed for the 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 (for effects on symptoms control and prevention of exacerbations see section 5.1).[2,9]
The therapy in pMDI device is also licensed for the maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.[9]

For a full list of side effects and information on dosage and administration, contraindications and other precautions, please refer to https://www.ema.europa.eu/ for further information.

## About COPD

COPD is a respiratory disease characterized by a persistent bronchial obstruction, associated with an increased chronic inflammatory response of the airways to noxious particles or gas. The classic symptoms associated with COPD are dyspnea, chronic cough and chronic productive sputum. In some cases, an acute worsening of the above-mentioned symptoms may occur, triggering an exacerbation. In the adult population aged over 40 years, moderate and severe COPD is prevalent in 5-10% of the population, and including mild cases, the prevalence is 15-20%. There are 300,000 deaths in Europe from COPD each year.[10]

## References


1. Trimbow.https://ec.europa.eu/health/documents/community-register/2021/20210407151230/dec_151230_en.pdf EMA marketing authorisation valid throughout the European Union, approved 07/04/2021. Available at: https://ec.europa.eu/health/documents/community-register/2021/20210407151230/dec_151230_en.pdf Accessed: April 2021.
2. Trimbow NEXThaler EMA SmPC. Available at: https://www.ema.europa.eu/en/documents/product-information/trimbow-epar-product-information_en.pdf Accessed: April 2021.
3. Trimbow, EMEA/H/C/004257, EMA marketing authorisation valid throughout the European Union, approved 17/07/2017. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/trimbow#authorisation-details-section. Accessed: March 2021.
4. Dekhuijzen PNR, Vincken W, Virchow JC et al, "Prescription of inhalers in asthma and COPD: Towards a rational, rapid and effective approach". Respir Med, 2013, Vol 107(12), pp 1817–21
5. Beeh K-M et al. Comparison of Dry-Powder Inhaler and Pressurized Metered-Dose Inhaler Formulations of Extrafine Beclomethasone Dipropionate/Formoterol Fumarate/Glycopyrronium in Patients with COPD: The TRI-D Randomized Controlled Trial. *International Journal of Chronic Obstructive Pulmonary Disease 2021:16 79–89*
6. Singh D, Papi A, Corradi M, et al. Single inhaler triple therapy *versus* inhaled corticosteroid plus long-acting β2-agonist therapy for chronic obstructive pulmonary disease (TRILOGY): a double-blind, parallel group, randomised controlled trial. *Lancet* 2016; 388: 963–973.
7. Vestbo J, Papi A, Corradi M, et al. Single inhaler extrafine triple therapy *versus* long-acting muscarinic antagonist therapy for chronic obstructive pulmonary disease (TRINITY): a double-blind, parallel group, randomised controlled trial. *Lancet* 2017; 389: 1919–1929.
8. Papi A, Vestbo J, Fabbri L, et al. Extrafine inhaled triple therapy *versus* dual bronchodilator therapy in chronic obstructive pulmonary disease (TRIBUTE): a double-blind, parallel group, randomised controlled trial. *Lancet* 2018; 391: 1076–1084.
9. Trimbow 87 micrograms/5 micrograms/9 micrograms pressurised inhalation, solution SmPC. Available at: https://www.medicines.org.uk/emc/product/761/smpc.
10. European Lung Foundation. COPD. Available at https://www.europeanlung.org/en/lung-disease-and-information/lung-diseases/copd. Last accessed March 2021


## Media contacts


Alessio Pappagallo
*Press Office Manager*
Phone +39 339 5897483,
Email a.pappagallo@chiesi.com


###