

Chiesi Carbon Minimal Inhalers reach new milestone with clinical phase III initiation

Published On: 2024-04-03 12:00

- *Chiesi Group announces a major step in the development of carbon minimal inhalers with the initiation of a new phase III long-term safety trial.*
- *The trial comes after the completion of two short-term clinical safety studies with the new low global warming potential propellant and three clinical pharmacology trials with a fixed dual combination.*
- *The carbon minimal inhalers aim at preserving the choice of device for patients suffering from asthma and COPD while reducing greenhouse gas emissions by up to 90%, when compared to existing metered dose inhalers, in anticipation of international and European environmental requirements.*

Parma (Italy), April 3, 2024 - Chiesi, the international, research-focused biopharmaceuticals and healthcare group (Chiesi Group), has started a [long-term phase III clinical safety trial](#) for the new carbon minimal inhalers platform, replacing the current hydrofluorocarbon propellant (HFC 134a) with a new, low global warming potential propellant (HFC 152a).

Chiesi has already completed two short term clinical trials assessing the safety of the new propellant^[1], plus three clinical pharmacology studies on the new carbon minimal fixed combination of an inhaled corticosteroid (ICS), and a long-acting bronchodilator (LABA). These studies collectively provided reassuring evidence of a similar performance and tolerability of the new formulation, when compared to the current one, for patients with asthma and COPD.

This milestone follows successful [completion of similar studies](#) in July 2022 with a fixed triple combination.

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death worldwide, and in 2019 caused 3.23 million deaths^[2]. In the same year, asthma affected an estimated 262 million people causing 455 000 deaths^[3]. Many COPD and asthma patients depend on pressurized-Metered Dose Inhalers (pMDIs) for treatment. However, there's debate about how much current propellants contained in pMDIs contribute to global warming. Efforts are underway to reduce their environmental impact^[4].

The development of the carbon minimal inhalers platform aims at enabling Chiesi to reduce emissions related to current products by up to 90% when compared to existing MDIs. This is a key step in our journey to achieve Net Zero greenhouse gas emissions by 2035, while preserving

asthma and COPD patients' needs.

*"At Chiesi, we strongly believe that patients should not have to bear the responsibility of environmental impact when considering treatment options that affect their health. The conclusion of these additional studies and the start of the phase III trial mark a significant milestone in our development of a new carbon minimal inhalers platform", stated **Giuseppe Accogli, CEO of Chiesi Group**. "We are confident that we can deliver carbon minimal solutions to patients without compromising safety, usability or efficacy".*

International guidelines for the treatment of both asthma and COPD support the concept of choosing the right medication and appropriate device for the patient to reduce their risk of severe exacerbations[5].

"We are dedicated to developing inhalers that meet patient needs while minimising environmental impact. By addressing climate change, one of the root causes of respiratory illness, we can simultaneously benefit patients and the planet," Accogli said.

About Chiesi Group

Chiesi is an international, research-focused biopharmaceuticals group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company's mission is to improve people's quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, and France, Chiesi's commitment to create shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, we're part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), operates in 31 countries, and counts more than 6,500 employees. The Group's research and development centre in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

[1] Clinical Trials. Study to Assess the Effect of the New HFA-152a Propellant on Mucociliary Clearance. Available from: <https://clinicaltrials.gov/study/NCT05875025A>;

Clinical Trials. Study to Compare the Effects of Two Propellants in Adults With Mild Asthma. Available from: <https://clinicaltrials.gov/study/NCT05472662>

[2] [https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-\(COPD\)](https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(COPD))

[3] <https://www.who.int/news-room/fact-sheets/detail/asthma>

[4] Pernigotti D, et al. . Reducing carbon footprint of inhalers: analysis of climate and clinical implications of different scenarios in five European countries. BMJ Open Respir Res. 2021 Dec;8(1):e001071. doi: 10.1136/bmjresp-2021-001071. PMID: 34872967; PMCID: PMC8650484.

[5] Global Initiative for Chronic Obstructive Lung Disease. 2024 Gold Report. Available at: <https://goldcopd.org/2024-gold-report/>.

Global Initiative for Asthma. 2023 Gina Main Report. Available at: <https://ginasthma.org/2023-gina-main-report/>.