

Chiesi's new carbon minimal pMDI propellant shows similar safety and tolerability profile as existing propellant

- Chiesi announces results of pharmacokinetic (PK) studies completed in May 2022 on an inhaler in development for the treatment of asthma and COPD, formulated with a new low global warming potential propellant.
- Results for the new propellant show a similar safety and tolerability profile when compared to the current propellant, ahead of next phase of development.^{1,2}
- Chiesi is on track to meet its timeline for the development of a carbon minimal pMDI by 2025, in line with NHS guidance outlined in its Long-Term Plan, in order to enable a seamless transition for patients while minimising the climate impact.³

MANCHESTER, UK, 21st September 2022 – Chiesi, the international research-focused biopharmaceutical and healthcare group, has announced new trial data for its carbon minimal pressurised Metered Dose Inhaler (pMDI) to treat asthma and Chronic Obstructive Pulmonary Disease (COPD), demonstrating a similar safety and tolerability profile as the existing propellant. Back in 2019, Chiesi committed €350 million to develop a new pMDI by 2025, replacing the current hydrofluorocarbon propellant (HFA-134a) with a new propellant (HFA-152a).⁴ Due to the low global warming potential of the new propellant, Chiesi will reduce its scope 3 or indirect greenhouse gas emissions, including the use of its pMDI products, by 90% in 2035.⁵

The two phase I trials completed in May 2022. One trial of healthy volunteers investigating the use of HFA-152a in a placebo pMDI showed it was well tolerated, had minimal impact on taste and was rapidly cleared from the blood, with no adverse effects reported.¹ A further trial of healthy volunteers provided evidence of similar systemic exposure, safety and tolerability in HFA-152a when compared to the current propellant, and no adverse effects leading to treatment discontinuation were reported.²

Chiesi entered into a commercial agreement with Koura Global, the leading medical propellant manufacturer, in 2019 to supply HFA-152a for inhalation product development, clinical trials and eventually for market placement. The final reports for these particular studies will be completed later this year.

Chiesi is committed to maintaining access to the range of treatment options that asthma and COPD patients need globally. As a certified B Corp, Chiesi innovates to find well-tolerated and environmentally conscious solutions and shares the ambition of the NHS to reduce the carbon emissions linked to inhalers on its path to becoming carbon net-zero by 2040.⁶

With these new studies completed, Chiesi is on track to meet the timeline for completing the development of the new product, in order to enable a seamless transition for patients from 2025.

Alessandro Chiesi, Chief Commercial Officer at Chiesi Group, said: *“With these results, we have reached a very important milestone in our Carbon Minimal Inhalers programme and on the road to fulfil our climate commitments on scope 1, 2 and 3 emissions by 2035. This is a key step forward in our plan; we are fully on track and really reassured that our work to date has been successful. We will continue prioritising #ActionOverWords in the fight against climate change and in ensuring that this never compromises the quality of care we provide our patients.”*

Dr Stuart Corr, Techno-Commercial Director at Koura, said: *“In looking for an alternative, more environmentally sustainable pMDI propellant, we took the view that any candidate should be as well-tolerated for the patients to use as the current propellants, HFA-134a and HFA-227ea. We are delighted with the results to date, all of which indicate that HFA-152a will meet this criterion.”*

Last year, the Economist Intelligence Unit published a report which rang a warning bell to highlight the devastating impact of climate change on respiratory health.⁷ By focusing on patients, and those suffering the health consequences of the climate crisis, Chiesi wants to help prevent this major health threat and promote a greater understanding and collaboration between sustainability and health experts. To achieve this, Chiesi intends to not only address the effects of the crisis through its commitment in delivering respiratory products to patients, but also to focus on the root causes by constantly improving its own environmental and social impact. This new propellant will play a significant part in this mission.

Chiesi Group reduction targets have been approved by the Science Based Target Initiative (SBTi) and are aligned with the Paris Agreement's most ambitious goal to limit global temperature rise to 1.5°C above pre-industrial levels by 2100. In May 2021, Chiesi Group reinforced its targets with the [#ActionOverWords](#) campaign to encourage measurable sustainability commitments and invite accountability.

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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. Since 2019, Chiesi is the world's largest biopharmaceutical group to be certified B Corp, meaning that its sustainability efforts are measured and assessed by the most ambitious global standards. The company aims at becoming net-zero by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), operates in 30 countries, and counts more than 6,000 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.

For further information please visit www.chiesi.co.uk

About B Corp®

B Corp® companies meet the highest standards of certified social and environmental performance, public transparency and legal responsibility, attempting to achieve the perfect balance between profit and sustainable objectives.

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⁷ Economist Impact. Climate change and its impact on lung health: a focus on Europe. Available at: <https://impact.economist.com/perspectives/healthcare/climate-change-and-its-impact-lung-health-focus-europe>. Accessed August 2022