

First carbon minimal pMDI is on track with the goal to benefit patients and planet

Published On: 2022-07-27 00:00

- *Chiesi Group announces positive results of pharmacokinetic (PK) studies completed in May 2022 on a leading inhaler in development for the treatment of asthma and COPD, formulated with a new low global warming potential propellant.*
- *Promising results with the new formulation show a similar profile when compared to the current formulation, ahead of next phase of development.*
- *Chiesi is on track to meet the timeline for the development of a carbon minimal pMDI in line with the ambition of the new European Commission F-gas regulation review proposal, in order to enable a seamless transition for patients, while minimizing the climate impact.*

Parma (Italy), 27 July 2022 – Back in [2019](#), Chiesi Group, the international research-focused biopharmaceutical and healthcare group, committed €350 million to develop the first carbon minimal pressurised Metered Dose Inhaler (pMDI) to treat asthma and Chronic Obstructive Pulmonary Disease (COPD) by 2025, replacing the current hydrofluorocarbon propellant (HFA 134a) with a new propellant (HFA-152a). 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.

In May 2022, two phase I trials were completed. The new formulation provided evidence of similar lung deposition, systemic exposure, safety and tolerability when compared to the current one. These studies achieved their goal in confirming that the development of HFA-152a was so far successful and the new product is suitable to continue the planned clinical-regulatory pathway.

Chiesi Group 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.

Koura is also progressing in its programme to demonstrate that the new HFA152a propellant is safe for human use, a critical element in choosing a next generation propellant for MDIs. The few remaining aspects of the programme and the final reports will be completed later this year. Results are reassuring so far, including a propellant-only HFA-152a [clinical trial](#) involving healthy volunteers, which raised no concerns regarding taste, odour or acceptability, and no adverse effects were reported.

Earlier this year, the European Commission published its [proposal](#) to review the 2014 fluorinated greenhouse gas (F-gas) regulation, which includes a gradual phase down of climate-damaging F-gases in the EU. Previously medical uses of F-gases, such as pMDIs, were exempt from this phase down, but the new proposal removes this exemption.

Chiesi Group 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 safe and environmentally conscious solutions and shares the ambition of the European Commission to reduce the carbon emissions linked to F-gases (including hydrofluorocarbons) on the EU's road to climate neutrality by 2050.

With the PK 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 and to benefit the planet. While in full support of the F-gas phase down strategy, Chiesi calls on the Commission to ensure that this does not compromise patient care and choice by considering the unpredictability of pharmaceutical development and the uncertainties of the regulatory approval process for medical products.

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 safe for the patients to use as the current propellants, HFA-134a and HFA-227ea. We are delighted with the results for HFA-152a 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. 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.

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.com

Contacts for media:

Carla Arrieta Martinez

Head of Global External Communication & Media Relations

Tel: +39 340 8879754

Email c.arrieta@chiesi.com

Alessio Pappagallo

Press Office Manager

Tel: +39 339 5897483

Email a.pappagallo@chiesi.com

