

# GRIFOLS

## Grifols completes Cohort 1 in clinical study of Alpha-1 15%, evaluating first-in-human subcutaneous dosing option for patients with alpha<sub>1</sub>-antitrypsin deficiency

- *Study designed to demonstrate impact of Alpha1-Proteinase Inhibitor Subcutaneous (Human) 15% (Alpha-1 15%), an alpha<sub>1</sub> antitrypsin treatment, compared with Liquid Alpha1-Proteinase Inhibitor (Human) intravenous*
- *This first in-human subcutaneous approach to treating alpha<sub>1</sub>-antitrypsin deficiency, if proven successful in clinical trials, could give patients the convenience and flexibility to administer their medication from home*

**Barcelona, Spain, November 15, 2023** – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world’s leading producers of plasma-derived medicines, today announced that it has completed Cohort 1 of its Phase 1/2 study ([NCT04722887](https://clinicaltrials.gov/ct2/show/study/NCT04722887)) evaluating Alpha1-Proteinase Inhibitor Subcutaneous (Human) 15% (Alpha-1 15%), a subcutaneous (SC) alpha<sub>1</sub> antitrypsin (AAT) treatment being compared to Liquid Alpha1-Proteinase Inhibitor (Human) intravenous (IV).

Alpha<sub>1</sub>-antitrypsin deficiency (also known as alpha-1) is an underdiagnosed<sup>1</sup> genetic disorder that occurs when a patient has low levels of AAT, a protective protein that safeguards the lungs. Augmentation therapy with IV AAT is the standard medical treatment option for patients with severe AAT deficiency and emphysema. If proven successful in clinical trials, a SC option could provide alpha-1 patients the ability to independently administer AAT therapy from home, allowing for greater convenience and flexibility.

In this multi-center, single-dose and repeat-dose study over eight weeks, Cohort 1 has been completed and demonstrated no safety issues with Alpha-1 15% that would prevent the study from moving forward into Cohort 2.

“A subcutaneous option would be a first for alpha-1 patients, providing more freedom when it comes to managing their AAT deficiency by allowing patients to administer their medication from the comfort of their own home. We are pleased to announce this milestone during Alpha-1 Awareness Month, contributing to raising further visibility about this rare disease,” said Jörg Schüttrumpf, Chief Scientific Innovation Officer, Grifols. “We look forward to moving this study into Cohort 2. Grifols has a strong commitment to the alpha-1 community and continues to

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<sup>1</sup> American Thoracic Society; European Respiratory Society. American Thoracic Society/European Respiratory Society statement: standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. *Am J Respir Crit Care Med.* 2003;168(7):818-900. doi:10.1164/rccm.168.7.818

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innovate to find additional treatment options for patients living with this disease, in addition to more convenient alpha-1 testing alternatives such as AlphaID™ At Home, our recently launched direct-to-consumer genetic health risk service.”

“During Alpha-1 Awareness month, we are excited to share this exciting news to the Alpha-1 community of a new clinical trial advancement in Alpha-1. We are thrilled that Grifols has completed Cohort 1 in clinical study of Alpha-1 15% and moving forward into Cohort 2. This study evaluating first-in-human subcutaneous dosing option for Alpha-1 patients could provide a new option that could easily be administered from their own homes,” said Scott Santarella, Alpha-1 Foundation President and CEO.

## About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals to enhance quality of life. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 390 across North America, Europe, Africa and the Middle East and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. It provides high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 24,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2022, Grifols' economic impact in its core countries of operation was EUR 9.6 billion. The company also generated 193,000 jobs, including indirect and induced.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information, please visit [www.grifols.com](http://www.grifols.com)

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