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Grifols completes enrollment of second cohort in first-in-human Alpha-1 15% subcutaneous option for treating alpha$_1$-antitrypsin deficiency

- ***After cohort 1 demonstrated positive safety and tolerability of Alpha1-Proteinase Inhibitor Subcutaneous (Human) 15% (Alpha-1 15%), cohort 2 will evaluate a higher dose per study protocol***

- ***If approved, this potentially first-ever subcutanous treatment for alpha$_1$-antitrypsin deficiency would provide patients the added convenience and flexibility to adminster their medication from home***

- ***Grifols continues to broaden and diversify its innovation portfolio based on patient needs and longstanding plasma science that delivers new indications and administration alternatives***

Barcelona, Spain, Feb. 18, 2025 - Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading manufacturer of plasma-derived medicines, today announced it has finished recruiting the second cohort of its Phase 1/2 study (NCT04722887) evaluating the safety and tolerability of two different doses of Alpha1-Proteinase Inhibitor Subcutaneous (Human) 15% (Alpha-1 15%) as a subcutaneous (SC) option for the treatment of alpha$_1$-antitrypsin (AAT) deficiency, compared to Liquid Alpha1-Proteinase Inhibitor (Human) intravenous (IV).

Cohort 2 patients will receive a 180 mg/kg dose of SC Alpha-1 15%, after treatment of cohort 1 patients with 72 mg/kg of SC Alpha-1 15% showed a good safety profile. The last patient, last visit for cohort 2 of this multi-center, single dose followed by repeat-dose study over eight weeks is expected in late summer 2025.

AAT deficiency is an underdiagnosed[1] 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. A

[1] 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

SC option could provide AAT patients the ability to independently administer their treatments from home, enabling greater convenience and flexibility.

“We are excited about the possibility of providing alpha-1 patients with a subcutaneous alternative, giving them more freedom when managing their AAT condition,” said Dr. Jörg Schüttrumpf, Grifols Chief Scientific Innovation Officer. “Our commitment to the Alpha-1 community remains unwavering and we continue applying our expertise in plasma science and plasma proteins to innovate new treatment options for patients.”

Grifols’ longstanding commitment to the Alpha-1 community also includes the diagnostic test AlphaID™, designed to detect the most prevalent variants associated with alpha$_1$-antitrypsin deficiency, also known as genetic chronic obstructive pulmonary disorder, a serious respiratory ailment. In 2023, Grifols launched its AlphaID™ At Home service, enabling U.S. adults to screen for the genetic risk of AAT deficiency without prescription from a healthcare professional. Since then, approximately 70,000 tests have been ordered.

“The Alpha-1 Foundation applauds Grifols for their continued commitment to the Alpha-1 patient community,” said Scott Santarella, President & CEO, Alpha-1 Foundation. “Their dedication to providing patients with innovative new treatment options could provide them with flexibility and convenience in managing their weekly vital treatments for AATD. Our thanks to Grifols for this outstanding investment. It is crucial for our community to have continued access to this lifesaving plasma therapy.”

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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. 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 23,000 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.

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 about Grifols, please visit grifols.com