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Grifols meets enrollment target in phase 3 study of two dose regimens of Prolastin®-C in patients with emphysema due to alpha-1-antitrypsin deficiency

- ***Target of 339 patients enrolled has been met in the SPARTA clinical trial, designed to evaluate efficacy and safety of two separate weekly doses of Grifols' Prolastin®-C (Alpha1-Proteinase Inhibitor [Human]) to slow emphysema progression in patients with alpha-1-antitrypsin (AAT) deficiency (known as alpha-1)***

- ***Alpha-1 is the most common genetic risk factor for chronic obstructive pulmonary disease (COPD), a group of respiratory diseases that includes emphysema. COPD is the third leading cause of death worldwide[1]***

- ***Grifols' advances in the science of alpha-1 underscore its robust innovation pipeline and commitment to testing and treatment for the alpha-1 community***

Barcelona, Spain, July 13, 2023 – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world's leading producers of plasma-derived medicines, today announced it has met its enrollment target of 339 patients in SPARTA (Study of ProlAstin-c Randomized Therapy with Alpha-1 augmentation; NCT01983241), its phase 3 clinical trial designed to determine if alpha-1- antitrypsin (AAT) deficiency (alpha-1) patients with emphysema have a slower progression of lung tissue loss when treated weekly with two separate dose regimens of Grifols Prolastin®-C.

Alpha-1 is an underdiagnosed[2] genetic disorder that can result in chronic obstructive pulmonary disease (COPD), a group of respiratory diseases that includes emphysema, which can occur when a patient has low levels of alpha-1 antitrypsin (AAT), a protective protein that safeguards the lungs. The currently approved dosage is 60 mg/kg in weekly infusions.

SPARTA, the largest randomized, double-blind, placebo-controlled study on AAT augmentation therapy to-date, is designed to evaluate the potential of Prolastin®-C to significantly reduce emphysema progression in alpha-1 patients by raising AAT protein levels through weekly administration of two active dose levels versus placebo.

The clinical trial is taking place across 16 countries and more than 50 sites. It will evaluate the efficacy and safety of two separate dose regimens of Prolastin®-C (60 and 120 mg/kg/week)

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[1] Lozano R, Naghavi M, Foreman K, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet.* 2012;380(9859):2095-2128. doi: 10.1016/S0140-6736(12)61728-0

[2] 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

versus placebo for 156 weeks (i.e., three years), measuring the rate of pulmonary-tissue loss through whole lung computed tomography (CT) densitometry as the primary measure of clinical efficacy.

“While alpha-1 patients currently benefit from recommended AAT augmentation therapy, we hope to show clinical evidence of benefit with the current approved dose and a greater impact by doubling the single dose to 120 mg/kg weekly,” said Sandra Camprubi, Grifols Senior Director Clinical Operations. “We look forward to providing topline data from this study in 2026 and evaluating the next regulatory steps to provide emphysema patients impactful treatment options for alpha-1.”

The company’s robust innovation pipeline includes a strong commitment to supporting the alpha-1 community. Earlier this year, Grifols launched its AlphaID™ At Home Genetic Health Risk Service (AlphaID™ At Home), the first-ever free direct-to-consumer program in the U.S. to screen for the genetic risk of alpha-1.

About Alpha-1 and COPD

Alpha-1-antitrypsin deficiency, also known as alpha-1, is a rarely diagnosed genetic disease that can result in chronic obstructive pulmonary disease (COPD), a group of respiratory diseases that includes emphysema, a lung condition that causes shortness of breath. Patients who have alpha-1 have a genetic deficiency of alpha-1 antitrypsin, a protective plasma protein that safeguards the lungs from inflammation caused by infection and inhaled irritants such as tobacco smoke. Alpha-1 is the major known genetic risk factor for COPD[3].

About Prolastin®-C

PROLASTIN®-C is an alpha1-proteinase inhibitor (human) (alpha1-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha1-PI (alpha-1-antitrypsin deficiency).

PROLASTIN®-C is contraindicated in immunoglobulin A (IgA)-deficient patients with antibodies against IgA or patients with a history of anaphylaxis or other severe systemic reaction to alpha1-PI products. Hypersensitivity reactions, including anaphylaxis, may occur. Monitor vital signs and observe the patient carefully throughout the infusion. If hypersensitivity symptoms occur, promptly stop PROLASTIN®-C infusion and begin appropriate therapy. Because PROLASTIN®-C is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens. The most common drug-related adverse reaction observed at a rate of >5% in subjects receiving PROLASTIN®-C was upper respiratory tract infection. The most serious adverse reaction observed during clinical trials with PROLASTIN®-C was an abdominal and extremity rash in 1 subject.

For full US Prescribing Information, please visit:
https://grifolsug-pi.com/inserts/Prolastin-C.pdf

Always refer to the Summary of Product Characteristics (SmPC) and the local prescribing information of your country.

[3] What causes alpha-1 antitrypsin deficiency? National Heart, Lung, and Blood Institute website. https://www.nhlbi.nih.gov/health/health-topics/topics/aat/causes. Updated October 11, 2011. Accessed June 28, 2023.

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.

MEDIA CONTACT:

Media Press Office
media@grifols.com
Tel. +34 93 571 00 02

INVESTORS:
Investors Relations Department & Sustainability
inversores@grifols.com - investors@grifols.com
Tel. +34 93 571 02 21

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