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# Grifols announces Last Patient Last Visit in SPARTA, its Phase 3 Outcomes Study of Prolastin®-C in patients with emphysema due to alpha-1 antitrypsin deficiency

- ***Grifols' SPARTA phase 3 trial is designed to evaluate the clinical efficacy and safety of two separate weekly dose regimens of Grifols' Prolastin®-C (Alpha1-Proteinase Inhibitor [Human] modified process) in patients with emphysema due to alpha-1 antitrypsin (AAT) deficiency (known as alpha-1)***
- ***The trial is the largest randomized, double-blind, placebo-controlled study on alpha-1 and augmentation therapy to-date and has the potential to provide clinical evidence on slowing progression of lung tissue loss in this patient group***
- ***This milestone marks the completion of follow-up for all 345 participants enrolled across 37 sites in 16 countries***
- ***Top line results expected by the end of 2026***
- ***Grifols continues to advance scientific innovation in alpha-1 through a comprehensive approach that includes disease awareness, genetic testing, clinical research and treatment***

***Barcelona, Spain, August 10, 2026 –*** Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading producer of plasma-derived medicines, today announced the completion of the clinical portion of SPARTA (**S**tudy of **P**rol**A**stin-C **R**andomized **T**herapy with **A**lpha-1 augmentation; NCT01983241), its phase 3 outcomes study evaluating the clinical efficacy and safety of two dose regimens of Prolastin®-C (Alpha1-Proteinase Inhibitor [Human] modified process) in patients with emphysema associated with alpha-1 antitrypsin deficiency (AATD), also known as alpha-1.

The last patient in the trial completed their final study visit last week. This milestone, known as "last patient, last visit" (LPLV) signifies completion of follow-up for all 345 enrolled participants. Topline results are expected by the end of this year.

Alpha-1 is a genetic disorder that can result in chronic obstructive pulmonary disease (COPD), a group of respiratory diseases that include emphysema, which can occur when a patient has low levels of AAT, a protective protein that safeguards the lungs. Alpha-1 remains significantly underdiagnosed[1] worldwide despite being the most common known genetic risk factor for COPD.

SPARTA is the largest randomized, double-blind, placebo-controlled study conducted to date in augmentation therapy for alpha-1 patients with emphysema. The trial was designed to evaluate the efficacy and safety of weekly administration of two active dose levels of Prolastin-C (60 mg/kg and 120 mg/kg) compared with placebo over a three-year treatment period.

[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

The study was conducted across 37 clinical sites in 16 countries and used whole-lung computed tomography (CT) densitometry as its primary efficacy endpoint. CT densitometry is considered the most sensitive method for detecting emphysema progression and quantifying lung tissue loss in patients with AATD[2], making SPARTA the first and only three-year study in AATD to generate longitudinal clinical evidence using this biomarker.

“The completion of patient follow-up in SPARTA marks a significant milestone for Grifols and the alpha-1 community,” said Eduardo Herrero, Grifols’ Executive Vice President Biopharma Industrial and Scientific Innovation. “We are deeply grateful to the patients, investigators and study teams whose dedication made this achievement possible. As the first and only prospective, double-blind, placebo-controlled three-year CT densitometry study in alpha-1-related emphysema, SPARTA reflects our long-standing commitment to people living with alpha-1 through innovation in testing, diagnosis and treatment.”

In addition to the SPARTA study, Grifols recently began the SWIFT-SC trial (NCT07555483), the first Phase 3 trial evaluating a weekly subcutaneous alpha1-proteinase inhibitor for the treatment of AATD. These clinical trials demonstrate the company’s ongoing commitment to innovation and to improving therapeutic options and long-term outcomes for patients with 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).

Limitations of Use

- The effect of augmentation therapy with any alpha1-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available
- PROLASTIN-C LIQUID is not indicated as therapy for lung disease in patients in whom severe alpha1-PI deficiency has not been established

[2] Miravitlles M et al.European Respiratory Society statement: diagnosis and treatment of pulmonary disease in alpha-1 antitrypsin deficiency. Eur Respir J. 2017

[3] Sandhaus RA, Turino G, Brantly ML, et al. *The Diagnosis and Management of Alpha-1 Antitrypsin Deficiency in the Adult*. J COPD Foundation. 2016;3(3):668-682.

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 adverse reaction during clinical trials in > 5% of subjects 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.

Please see full US Prescribing Information for Prolastin-C.

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

**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 focuses on treating conditions centered on six core therapeutic areas: immunology, neurology, pulmonology, hematology, hepatology and intensive care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's most diversified with more than 400 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 25,000 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 www.grifols.com.

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