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Grifols doses first participant in Phase 3 study evaluating novel subcutaneous therapy for alpha$_1$-antitrypsin deficiency

- ***First-of-its-kind Phase 3 study to evaluate weekly subcutaneous Alpha1-Proteinase Inhibitor, a novel approach, compared to standard intravenous therapy***
- ***SWIFT-SC is an open-label, multicenter, randomized trial***
- ***Positive outcome could expand treatment flexibility for patients***

Barcelona, Spain, June 29, 2026 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading producer of plasma-derived medicines, today announced the enrollment of the first patient in its Phase 3 SWIFT-SC clinical trial, a global study designed to evaluate a novel subcutaneous (SC) formulation of Alpha$_1$-Proteinase Inhibitor (Alpha$_1$-PI) for the treatment of alpha$_1$-antitrypsin (AAT) deficiency.

The SWIFT-SC study (NCT07555483) "An Open-Label, Multicenter, Randomized, Non-Inferiority Pharmacokinetic and Safety/Tolerability Study of Two Different Weekly Doses of Alpha$_1$-Proteinase Inhibitor Subcutaneous (Human) 15% in Patients With Alpha$_1$-Antitrypsin Deficiency Compared to Corresponding Standard 60 mg/kg/Week and 120 mg/kg/Week Doses of Intravenous Alpha$_1$-Proteinase Inhibitor (5%)" will compare two different weekly doses of subcutaneous Alpha-15% with corresponding standard intravenous Alpha$_1$-PI doses.

The trial's short name, SWIFT-SC, stands for **S**ubcutaneous; **W**eekly dosing; Alpha$_1$ proteinase **I**nhibitor **F**ormulation-focused; clinical **T**rial – subcutaneous (SC), representing the aim of the study. The purpose of SWIFT-SC is to determine whether the subcutaneous formulation demonstrates non-inferior pharmacokinetics compared to intravenous therapy, while also evaluating safety and tolerability. Adult participants with AAT deficiency will be randomly assigned to two treatment groups in this open-label study.

Advancing toward more flexible treatment options

SWIFT-SC is the first Phase 3 clinical trial to evaluate subcutaneous augmentation therapy in patients with AAT deficiency. This trial builds on the successful completion of the Phase 1/2 study, NCT04722887, sponsored by Grifols. The investigational therapy uses a 15% concentration, approximately three times higher than the standard intravenous formulation, enabling delivery via subcutaneous administration.

Subcutaneous administration of medicines may provide meaningful benefits for patients by enabling self-administration outside of clinical settings, reducing reliance on infusion centers or home healthcare visits, and providing greater flexibility in when and where treatment is administered.

"Advancing treatment approaches is an important step forward for patients living with alpha$_1$-antitrypsin deficiency," said Eduardo Herrero, Grifols' EVP Biopharma Industrial and Scientific Innovation. "With SWIFT-SC, we are exploring the potential to expand treatment options to deliver Alpha$_1$-PI therapy in a way that best aligns with individual patient preferences."

Building on ongoing Alpha-1 research

SWIFT-SC complements Grifols' broader clinical program in AAT deficiency, including the ongoing SPARTA study (NCT01983241), which is the largest prospective, randomized, double-blind, placebo-controlled study to date designed to provide computed tomography (CT) densitometry efficacy data on the impact of plasma-derived augmentation therapy for AAT deficiency. SPARTA is expected to complete in the second half of this year, with top-line results anticipated by year-end. Together, these studies reflect Grifols' commitment to advancing innovative therapeutic options and improving long-term outcomes for patients with AAT deficiency.

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[1].

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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[1] 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.

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