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Grifols completes enrollment in phase 3 study of long-term Albutein® (albumin-human injection) therapy for patients with decompensated cirrhosis

- *PRECIOSA clinical trial is designed to evaluate efficacy and safety of Grifols Albutein® plus standard medical treatment to increase survival time in patients with decompensated cirrhosis awaiting transplant*
- *Albumin's antioxidant and anti-inflammatory properties have the potential to mitigate the complications associated with decompensated cirrhosis*
- *Grifols continues innovating across its plasma-protein franchise and is committed to applying its ever-growing expertise in a range of therapeutic areas to help treat pressing societal healthcare challenges*

Barcelona, Spain, July 18, 2023 – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world's leading producers of plasma-derived medicines, today announced it has completed enrollment in PRECIOSA ([NCT03451292](https://clinicaltrials.gov/ct2/show/study/NCT03451292)), its phase 3 clinical trial designed to determine the potential of long-term albumin treatment with Grifols Albutein® to increase survival time in patients with decompensated cirrhosis and ascites until a suitable transplant is available.

Cirrhosis, a condition in which the liver is permanently scarred and can lead to liver failure, is the leading cause of liver-related deaths globally,¹ with more than 1.32 million deaths reported in 2017.² In the U.S. alone, researchers estimate that about 1 in 400 adults have cirrhosis,³ including those who have progressed into decompensated cirrhosis once complications such as ascites appear. Ascites is a buildup of fluid in the abdomen and signals that a patient's risk for poor outcomes, including death, have significantly increased.

Albumin, the most abundant protein in plasma, has antioxidant and anti-inflammatory properties with the potential to mitigate the complications associated with decompensated cirrhosis and its progression into the next stage of the disease, acute-on-chronic liver failure (ACLF). Treatment

¹ GBD 2017 Causes of Death Collaborators. Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 2018;392(10159):1736-1788. doi:10.1016/S0140-6736(18)32203-7

² GBD 2017 Cirrhosis Collaborators. The global, regional, and national burden of cirrhosis by cause in 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet Gastroenterol Hepatol*. 2020;5(3):245-266. doi:10.1016/S2468-1253(19)30349-8

³ Scaglione S, Kliethermes S, Cao G, et al. The Epidemiology of Cirrhosis in the United States: A Population-based Study. *J Clin Gastroenterol*. 2015;49(8):690-696. doi:10.1097/MCG.000000000000208

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with albumin has the potential to reduce the high one-year mortality rates observed in decompensated cirrhosis.

Over 400 patients with decompensated cirrhosis with ascites are participating in this multi-center, randomized (1:1), controlled, parallel-group, open-label study in 69 sites across North America and Europe. It will evaluate the efficacy and safety of long-term Albutein® administration (dosed every 10 ± 2 days for up to 12 months) plus standard medical treatment.

“There is great potential for albumin to improve the survival prospects of patients suffering from decompensated cirrhosis until they can get a liver transplant, a large unmet need given the limited availability of livers for patients,” said Sandra Camprubi, Grifols Senior Director Clinical Operations. “We look forward to providing topline data from this study in the fourth quarter of 2024 and evaluating next regulatory steps to provide patients with a much-needed treatment.”

Grifols is committed to strengthening its innovation pipeline, which consists of multiple plasma and non-plasma programs across various clinical stages, all dedicated to potential treatments to help patients live longer, better-quality lives.

About Decompensated Cirrhosis and Ascites

Chronic liver disease is an all too common and growing problem in the developed world, with worldwide prevalence rates of around 20%.⁴ One such condition is cirrhosis, in which the liver is permanently scarred and, in many cases, can lead to liver failure. Decompensated cirrhosis is defined by the complications that can occur in a patient with cirrhosis, which include ascites, variceal bleeding, hepatic encephalopathy, and bacterial infections. These complications are associated with worse survival (2-4 years) compared with compensated cirrhosis (10-15 years).⁵

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

⁴ Moon AM, Singal AG, Tapper EB. Contemporary epidemiology of chronic liver disease and cirrhosis. *Clin Gastroenterol Hepatol.* 2020;18(12):2650-2666. doi: 10.1016/j.cgh.2019.07.060

⁵ López-Sánchez GN, Dóminguez-Pérez M, Uribe M, Nuño-Lámbardi N. The fibrogenic process and the unleashing of acute-on-chronic liver failure. *Clin Mol Hepatol.* 2020;26(1):7-15. doi:10.3350/cmh.2019.0011; Fanali G, di Masi A, Trezza V, Marino M, Fasano M, Ascenzi P. Human serum albumin: from bench to bedside. *Mol Aspects Med.* 2012;33(3):209-290. doi:10.1016/j.mam.2011.12.002

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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).

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