GRIFOLS

Grifols achieves positive results from phase 4 study of Fanhdi® (double-inactivated human anti-hemophilic factor) in patients with von Willebrand Disease

- ***Grifols' Fanhdi showed it could be effective, safe and well tolerated in the management of bleeding episodes and for the prevention of bleeding during surgeries in patients with von Willebrand Disease (VWD)***

- ***VWD, which is caused by a deficiency of von Willebrand factor in plasma, is the most common hereditary blood-clotting disorder[1]***

- ***Grifols remains commited to providing innovative plasma therapies that treat a variety of life-threatening diseases and conditions that impact patients worldwide***

Barcelona, Spain, April 22, 2024 – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world's leading producers of plasma-derived medicines and a pioneer in rare disease treatment, today announced that its recently concluded observational phase 4 study of Fanhdi®, Grifols' double-inactivated human anti-hemophilic factor, showed positive results in the product's safety and efficacy as prophylaxis and treatment in patients with von Willebrand Disease (VWD). Grifols will present the data today at the World Hemophilia Federation 2024 World Congress, in Madrid.

VWD is an incurable bleeding disorder that affects the ability of blood to clot properly. It's the most common hereditary blood-clotting disorder and in Spain alone, this rare disease is estimated to impact 122 patients per million[2].

Grifols conducted this phase 4, observational, multi-center, prospective cohort study to evaluate the safety and clinical efficacy of long-term use of Fanhdi in subjects with VWD. The overall clinical efficacy of treatment with Fanhdi (including on-demand and prophylaxis) achieved 100% excellent and/or good (n=15 patients) rated by the investigator, with no safety concerns raised throughout the study.

"This observational study further reinforces the potential long-term effectiveness of Fanhdi in the treatment of bleeding episodes and as prophylaxis before surgical procedures," said Dr. Jörg Schüttrumpf, Grifols Chief Scientific Innovation Officer. "Grifols continues to develop and provide advanced lifesaving therapies for patients in need."

[1] Leebeek FW, Eikenboom JC. von Willebrand's disease. N Engl J Med. 2016;375(21):2067-2080. doi: 10.1056/NEJMra1601561
[2] Batlle J, Perez-Rodriguez A, Pinto JC, Fraga EL, Rodriguez-Trillo Tch A, Fernanda Lopez-Fernandez M. Diagnosis and management of von Willebrand disease in Spain. Semin Thromb Hemost. 2011;37(5):503-510. doi: 10.1055/s-0031-1281036

A total of 17 participants were enrolled in the 12-month study, 15 of them receiving at least one dose of Fanhdi®. The efficacy was assessed during 46 bleeding episodes reported for nine (60%) subjects, and six surgical/invasive procedures reported for six (33.3%) subjects.

About Fanhdi®

In the EU and other countries – though not in the United States – Antihemophilic Factor/von Willebrand Factor Complex (Human), Fanhdi®, is indicated for the prevention and control of bleeding in patients with Factor VIII deficiency due to hemophilia A. Fanhdi® is also indicated for surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease, except Type III undergoing major surgery, in whom desmopressin (DDAVP®) is either ineffective or contraindicated. Antihemophilic factor potency (Factor VIII:C activity) is expressed in International Units (IU) on the product label. Additionally, each vial of Fanhdi® also contains VWF:RCo activity in IU for the treatment of VWD. Fanhdi® is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components. Anaphylaxis and severe hypersensitivity reactions are possible. Development of activity-neutralizing antibodies has been detected in patients receiving FVIII containing products. Development of alloantibodies to VWF in Type 3 VWD patients has been occasionally reported in the literature. Fanhdi labeling may vary depending on 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 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, please visit www.grifols.com

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