GRIFOLS

FDA approves Grifols Prolastin®-C Liquid [alpha-1 proteinase inhibitor, liquid] for the treatment of alpha-1 antitrypsin deficiency

- ***Prolastin®-C Liquid is the first liquid formulation of an alpha-1 antitrypsin deficiency replacement therapy manufactured in the U.S. The new formulation marks an important milestone in Grifols' ongoing R&D efforts.***

- ***Alpha-1 antitrypsin deficiency is a rare genetic condition whose symptoms resemble other respiratory diseases.***

- ***Alpha-1 antitrypsin deficiency may lead to pulmonary emphysema without proper treatment and is the most common cause of liver disease in children. The disorder affects approximately 25 per 100,000 individuals[1].***

- ***Prolastin®-C Liquid is a ready-to-infuse liquid formulation that requires less preparation time as compared to the lyophilized product and less volume for infusion as compared to the alpha-1 of another competitor, offering a series of advantages for both patients and healthcare professionals.***

- ***Grifols also received recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for Grifols VeraSeal® (human fibrinogen/thrombin), a new product used for surgical operations in adults.***

Barcelona (Spain), September 22, 2017.- Grifols (MCE: GRF, MCE: GRF.P and NASDAQ:GRFS) announced the approval from the U.S. Food and Drug Administration (FDA) for a liquid formulation of its alpha-1 antitrypsin (Prolastin®-C Liquid) as a replacement therapy to treat alpha-1 antitrypsin deficiency (AATD). AATD is a rare genetic disorder that affects approximately 25 per 100,000 people[1] which can lead to pulmonary emphysema without adequate treatment. Moreover, it represents the most common cause of liver disease in children.

The FDA approval culminates an important R&D milestone for Grifols to create a new product formulation of alpha-1 antitrypsin. The approval process for the product has also commenced in Europe.

Prolastin®-C Liquid is the first liquid formulation of an alpha-1 antitrypsin deficiency replacement therapy manufactured in the U.S. This plasma-derived product will be also manufactured at Grifols' industrial complex in Parets del Vallès (Barcelona, Spain) following

[1] Source: Orphanet Report Series, Rare Diseases Collection, May 2014.

the same production process once the new alpha-1 purification and filling plant comes into operations. Grifols has invested EUR 45.4 million toward the new plant, which will have a production capacity of 4.3 million equivalent liters of plasma in both freeze-drying and liquid formulations.

A ready-to-infuse liquid formulation, Prolastin®-C Liquid provides several advantages for both patients and healthcare professionals since it requires less preparation time as compared to the lyophilized product and less volume for infusion (1g in 20mL) as compared to the Alpha-1 of another competitor. Until now, the product had only been offered in a lyophilized formulation. For more information on Prolastin®-C, including prescribing information, please visit: https://www.prolastin.com

The commercial launch of Prolastin®-C Liquid is scheduled for 2018.

Alpha-1 antitrypsin deficiency, an inherited and under-diagnosed disorder

Alpha-1 deficiency is an inherited disorder that causes a deficiency or absence of the alpha-1 protein in the plasma. It has a higher prevalence than other rare lung diseases such as cystic fibrosis and pulmonary arterial hypertension. While AATD symptoms vary depending on the degree of severity and type of genetic mutation, the most common is a progressive loss of pulmonary function.

Alpha-1-antitrypsin deficiency affects an estimated 25 cases per 100,000 people[1], although more than 90% of cases remain undiagnosed. In the U.S., approximately 100,000 people suffer from AATD, with similar numbers estimated in Europe. In Spain, roughly 10,000 to 12,000 people have alpha-1 antitrypsin deficiency.

Common symptoms of alpha-1 deficiency include dyspnea, or shortness of breath following physical exertion; chronic coughing; excessive mucous production; and wheezing, with or without the presence of respiratory infections. The symptomology of AATD concurs with that of chronic obstructive pulmonary disease (COPD), asthma, and other pulmonary diseases, leading many patients to be treated for other disorders while the root cause remains unaddressed.

Early diagnosis of AATD is vital. Without adequate treatment, patients are at risk for pulmonary emphysema, which can prove fatal without a lung transplant. AATD is also the most common cause of liver disease in children.

About Grifols

Grifols is a global healthcare company founded in 1940. Grifols has over 75 years improving people's health and wellbeing through the development of life-saving plasma medicines, diagnostics systems, and hospital pharmacy products.

The company is present in more than 100 countries worldwide and is headquartered in Barcelona, Spain. Grifols is a leader in plasma collection with a network of close to 180 plasma donor centers in the U.S., and a leading producer of plasma-derived biological medicines. The company also provides a comprehensive range of transfusion medicine, hemostasis, and immunoassay solutions for clinical laboratories, blood banks and transfusion centers, and is a recognized leader in transfusion medicine.

In 2016, sales exceeded 4,000 million euros with a headcount close to 15,000 employees. Grifols demonstrates its commitment to advancing healthcare by allocating a significant portion of its annual income to R&D.

The company class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE: GRF). Its non-voting class B shares are listed on the Mercado Continuo (MCE: GRF.P) and on the U.S. NASDAQ via ADRs (NASDAQ: GRFS). For more information visit www.grifols.com

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