

*Grifols further consolidates its research efforts*

## **FDA approval of genetic test for alpha-1 deficiency and EMA approval of fibrin sealant**

- ***Grifols, through Progenika Biopharma, has developed a latest-generation test capable of identifying the most common mutations associated with alpha-1 antitrypsin deficiency.***
- ***Alpha-1 antitrypsin deficiency is a genetic rare disease that can cause pulmonary emphysema. The disorder affects roughly 25 per 100,000 individuals<sup>1</sup> and an estimated 90% of cases remain undiagnosed.***
- ***On the other hand, the European Medicines Agency (EMA) has approved a new Grifols product, a biological sealant composed of human fibrinogen and thrombin for use in surgical interventions in adults.***

***Barcelona, November 17, 2017.-*** Grifols (MCE:GRF, MCE:GRF.P NASDAQ:GRFS) has received approval by the U.S. Food and Drug Administration (FDA) for a new genetic test to detect alpha-1 antitrypsin deficiency. The authorization marks an important milestone in the industry as it is the first time the FDA has approved a biological molecular test that uses the DNA of the patient for the diagnostic.

The FDA has approved the test for both DNA extracted from blood, as well as a drop of blood collected on paper (dry blood spot). *A1AT Genotyping Test*, developed by Progenika Biopharma, a Grifols subsidiary headquartered in Bilbao (Spain) is capable of simultaneously analyzing 99% of the most prevalent known mutations causing alpha-1 antitrypsin deficiency.

The molecular test analyzes simultaneously 192 samples per kit, and in a single reaction, identifies 14 of the most prevalent known mutations in the SERPINA1 gene, responsible for this genetic disorder. Although highly complex, the test has been designed so any molecular biology laboratory can process it with minimal human intervention.

*A1AT Genotyping Test* also has the CE marking from December 2016.

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<sup>1</sup> Source: Orphanet Report Series, Rare Diseases Collection, May 2014.

Grifols, global leader in the production and sale of alpha-1 antitrypsin, focus its growth strategy for this plasma protein on improving the diagnosis of the alpha-1 antitrypsin deficiency.

Grifols' portfolio of products already includes a diagnostic test that measures the level of this protein in the bloodstream. With this latest FDA approval, Grifols further consolidates its strategy and adds a new diagnostic test to continue actively advancing the diagnosis of alpha-1 antitrypsin deficiency in the United States, Europe, and more recently in Latin America.

The FDA approval also reinforces Grifols' strategy of promoting synergies among its business lines through the development of complementary products and services for its divisions.

## **New Fibrin Biological Sealant**

The European Commission, following a favorable recommendation from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), has approved a new Grifols product, a fibrin sealant composed of two plasma proteins (human fibrinogen and thrombin) for surgical use in adult patients.

Grifols obtained FDA approval for this product on November 1, 2017.

The recent approval of the product by the European and U.S. health authorities culminates an important R&D effort for Grifols, allowing it to expand its offer of plasma-derived products. The biological sealant will be manufactured at the Grifols industrial complex located in Parets del Vallès (Barcelona, Spain).

## **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<sup>1</sup>, 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, 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](http://www.grifols.com)

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