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Grifols study demonstrates higher dose of PROLASTIN-C increases levels of alpha$_1$-PI to within normal range in patients with AAT deficiency

Study results presented at annual meeting of American Thoracic Society (ATS)

Philadelphia, PA – (May 22, 2013) – Grifols, a global healthcare company based in Barcelona, Spain presented results from a study demonstrating that a higher dose of PROLASTIN©-C (Alpha$_1$-Proteinase Inhibitor [Human]) increased levels of the alpha$_1$ protein in patients with alpha$_1$antitrypsin (AAT) deficiency to levels that are considered within the normal range for healthy individuals. AAT deficiency is a life-threatening, genetic condition in which low levels of the alpha$_1$ proteinase inhibitor (A1PI) protein can lead to emphysema.

Results of the PROLASTIN-C SPARK study, a multidose pharmacokinetic clinical trial, were presented at the annual meeting of the American Thoracic Society (ATS) on May 21. Data from the study showed that weekly infusions of PROLASTIN-C at 120 mg/kg increased serum concentrations of the A1PI protein to proportionately higher levels than weekly infusions of 60 mg/kg, the currently approved dose of PROLASTIN-C. Furthermore, the 120 mg/kg dose raised serum concentrations of A1PI to the range of 20-53 µM, considered to be normal for healthy individuals. Both doses were safe and well tolerated in subjects with AAT deficiency.

“These data demonstrate that a 120 mg/kg dose of PROLASTIN-C provides closer to physiologic A1PI concentrations than the currently recommended 60 mg/kg dose and confirm the predictable PK profile of augmentation therapy” concluded Dr. Mark Brantly, Professor of Medicine, University of Florida College of Medicine.

Grifols is using data from the SPARK study as the basis to proceed with a larger, long-term study of the two doses of PROLASTIN-C. The trial, known as SPARTA, will be the first and only clinical trial to evaluate the efficacy of PROLASTIN-C at the standard 60/mg/kg dose and the 120 mg/kg dose vs. placebo. The SPARTA study will use CT lung densitometry to measure the degree of lung tissue preservation over time. The SPARTA study will be a multicenter trial and is scheduled to begin in the second half of 2013.

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About Grifols

Grifols is a global healthcare company with a 70-year legacy of improving people's health and well-being through the development of life-saving plasma medicines, hospital pharmacy products, and diagnostic technology for clinical use.

As a leading producer of plasma medicines, Grifols has a presence in more than 100 countries and is the world leader in plasma collection, with 150 plasma donation centres across the US. Grifols is committed to increasing patient access to its life-saving plasma medicines through significant manufacturing expansions and the development of new therapeutic applications of plasma proteins. The company is headquartered in Barcelona, Spain, and employs more than 12,000 people worldwide.

In 2012, Grifols' sales exceeded 2,620 million euros. The company's class A shares are listed on the Spanish Stock Exchange, where they form 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 US NASDAQ via ADRs (NASDAQ: GRFS). For more information visit www.grifols.com.

About Alpha$_1$-Antitrypsin Deficiency

Alpha$_1$-antitrypsin deficiency, also known as AAT deficiency or alpha-1, is an inherited disorder that causes a significant reduction in the naturally occurring protein, alpha$_1$-proteinase inhibitor. While rare, alpha$_1$ is the most common cause of genetic emphysema in adults and the most common cause of liver disease in children. Individuals suffering from alpha$_1$ often develop severe chronic obstructive pulmonary disease (COPD) leading to disability and premature death. Alpha$_1$ is estimated to affect 200,000 people in North America and Europe combined, although greater than 90% of individuals remain undiagnosed.

About PROLASTIN® and PROLASTIN®-C

PROLASTIN and PROLASTIN-C are indicated for the treatment of alpha$_1$-antitrypsin (AAT) deficiency in patients with emphysema. AAT deficiency is a genetic condition in which low levels of the alpha$_1$ protein can result in emphysema in adults and liver disease primarily in children. The active protein in PROLASTIN and PROLASTIN-C increases or augments protein levels in AAT-deficient patients. PROLASTIN is approved or registered in select countries in Europe and South America while PROLASTIN-C is approved in the US, Canada, Argentina and Colombia.

Important Safety Information about PROLASTIN®-C

PROLASTIN-C, Alpha$_1$-Proteinase Inhibitor (Human) is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to deficiency of alpha$_1$-proteinase inhibitor (alpha$_1$-antitrypsin deficiency).

The effect of augmentation therapy with any alpha$_1$-proteinase inhibitor (alpha$_1$-PI) on pulmonary exacerbations and on the progression of emphysema in alpha$_1$-antitrypsin deficiency has not been demonstrated in randomized, controlled clinical trials. PROLASTIN-C is not indicated as therapy for lung disease in patients in whom severe Alpha$_1$-PI deficiency has not been established.

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PROLASTIN-C may contain trace amounts of IgA. Patients with known antibodies to IgA, which can be present in patients with selective or severe IgA deficiency, have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. PROLASTIN-C is contraindicated in patients with antibodies against IgA.

The most common drug related adverse reactions during clinical trials in ≥1% of subjects were chills, malaise, headache, rash, hot flush, and pruritus. The most serious adverse reaction observed during clinical studies with PROLASTIN-C was an abdominal and extremity rash in one subject.

PROLASTIN-C is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see full Prescribing Information at http://www.talecris-pi.info/inserts/PROLASTIN-C.pdf

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.