

## Grifols Obtains FDA Approval for Flebogamma® DIF 10 % IVIG

- Grifols will be the first company that has two concentrations of intravenous liquid immunoglobulin (5 % and 10 %) in the United States.
- Since 2007 Grifols has offered a 5% IVIG concentration in the United States and plans to launch its new Flebogamma® DIF 10% at the end of 2010.
- Initially production of Flebogamma® DIF 10% will take place at the Company's facilities in Barcelona, Spain but may ultimately be transferred to new IVIG production facility in Los Angeles, California when that facility is completed some time in 2013.

*Barcelona, Spain (September 2, 2010).* Grifols, a global healthcare company specializing in biologic therapies derived from human plasma, has obtained US Food and Drug Administration (FDA) approval for its next generation of intravenous immunoglobulin (IVIG) 10% concentration, under the name Flebogamma® 10% DIF. With this approval, Grifols is the first company in the US to offer patients and clinicians two concentrations of liquid IVIG (5% and 10%). Offering two product concentrations that carry the trust and confidence of the Grifols name will allow healthcare providers to better meet patient needs. Grifols plans to launch Flebogamma® 10% DIF toward the end of 2010.

Grifols has marketed Flebogamma® DIF in a 5% concentration since 2007 and in Europe since 2008. The Company has already initiated the process of obtaining market authorization for Flebogamma® 10% DIF from the European Medicines Agency (EMA). This approval is expected in the fourth quarter of 2010.

Flebogamma® DIF is produced at Grifols facilities in Barcelona, Spain where the company has a production capability of approximately 13 million grams a year. Initiating full production of Flebogamma® 10% DIF at the Barcleona facilities is in line with the Company's production plans and long term growth strategy.

Flebogamma® DIF (Double Inactivation and Filtered) is a polyvalent IVIG that incorporates two specific viral inactivation methods and the additional safety step of nanofiltration at 20 nanometers. Years of research and development lead to the proprietary processes used to produce Flebogamma® 10% DIF. These processes have the benefit of higher product yeilds to maximize the amount of life-saving medicine that can be produced from each plasma donation.

## About Flebogamma® DIF 5% and 10%

Both Flebogamma® DIF 5% and 10% are high-purity products that remain stable at room temperature for the entire two-year shelf-life. This offers healthcare providers and patients greater convenience and ease of use.

Flebogamma® DIF 5% and 10% are approved in the US for replacement therapy in primary (inherited) humoral immunodeficiency disorders such as common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome.

## **About Grifols**

Grifols is a Spanish holding company specializing in the pharmaceutical - hospitable sector present in more than 90 countries. From 2006, it quotes on the Spanish Stock Market and it is a part of the Ibex-35 since 2008. At present, it is the leading European producer of plasma therapies and the fourth world-wide. Grifols has the insured a stable supply of plasma with 80 plasma donor centers in the United States. Grifols production capabilities at its facilities in Barcelona, Spain and Los Angeles, California allow Grifols to respond to increasing demand plasma therapies. The Company has already begun an aggressive eight to ten year growth plan with additional investments in plasma supply and production capacity.