

The European Medicines Agency grants marketing approval for this product, whose sales have already started in the United States

Grifols obtains EMA license to market its IVIG, Flebogamma[®] DIF, at 10% concentration

- **The approval means that Grifols now offers two concentrations of intravenous immunoglobulin (IVIG): 5% and 10%, allowing it to better respond to the needs of European health professionals and patients**
- **Grifols' patented production process, developed at its Barcelona plant, ensures the highest standards of product quality and safety**

Barcelona, 15 December 2010: Grifols obtains European Medicines Agency (EMA) license to market intravenous immunoglobulin (IVIG) at 10% concentration (Flebogamma[®] DIF 100 mg/ml). This approval arrives immediately after sales of this product have started in the United States.

Flebogamma[®] DIF 100 mg/ml is an IVIG at 10% concentration, allowing Grifols to offer two concentrations of the product in Europe (5% and 10%), both ready for administration. It will gradually be made available in all European Union countries, enabling Grifols to better attend to the needs of European health professionals and patients. The group began the sale of Flebogamma[®] DIF 50 mg/ml (5% concentration) in Europe in 2008.

This new immunoglobulin solution at 10% complies with the highest quality standards which Grifols applies to all its products. The manufacturing process patented by the company and developed at its Barcelona plant incorporates two different pathogen inactivation processes, in addition to a 20 nanometer filtration stage, which significantly increases the safety margins of Flebogamma[®] DIF 100 mg/ml, making it possible to obtain a high purity solution.

GRIFOLS

About Flebogamma[®] DIF

Flebogamma[®] DIF is a stable, polyvalent IVIG which can be stored at room temperature ($\leq 30^{\circ}\text{C}$) for up to two years, as a result of which no refrigeration is required during the product lifetime. This facilitates logistics, distribution and use of the product.

Grifols' commitment to quality and safety of all its hemoderivatives, is enhanced by using the very latest technology to guarantee the traceability of its products. As a result, each vial of Flebogamma[®] DIF is laser marked to ensure its authenticity, and each container includes a holographic seal on the opening flap.

In addition, Grifols gives its customers access to information about the origin of the plasma, analysis performed, and the characteristics of each product batch through its PediGri[®] website (pedigrionline.net). This is an exclusive service offered by Grifols to prescribing physicians, and it reflects the company's commitment to providing transparent information about the traceability and quality of its plasma products.

Flebogamma[®] DIF is especially indicated for replacement treatment in primary and secondary immunodeficiencies, and for immunomodulatory treatment in autoimmune diseases and allogenic bone marrow transplant.

About Grifols

Grifols is a Spanish holding company, specializing in the hospital-pharmaceutical sector, and with a presence in over 90 countries. Since 2006 it has been listed on the Spanish Continuous Market, and it has been included in the Ibex-35 index since 2008. Grifols is the leading European plasma products company, and the fourth-largest producer in the world. The company plans to strengthen its position within the industry as a vertically integrated company, on the basis of its ongoing investment program. In terms of raw material, Grifols has secure plasma supplies from its network of 80 plasmapheresis centers in the United States, while its production plants in Barcelona (Spain) and Los Angeles (United States) ensure that it has the fractionation capacity to satisfy rising demand. In addition, the company has implemented an ambitious investment plan to enable it to deliver sustained growth over the next 8 to 10 years.