

Presenting a new generation of intravenous immunoglobulin (IVIG), the result of the technological advances achieved by our R&D team

## Grifols licensed by the FDA to market a new generation of IVIG in the United States

- This new hemoderivative will be produced in the Spanish holding company's new IVIG plant in Barcelona.
- This next-generation IVIG, the result of a research, development, validation and registration effort spanning nearly a decade, will be marketed in the United States during 2007 under the name *Flebogamma*® *DIF*.

**Barcelona, December 27, 2006.** Grifols, a Spanish holding company specializing in the pharmaceutical and hospital industries, has been licensed by the U.S. Food and Drug Administration (FDA) to market a new generation of intravenous immunoglobulin (IVIG) in the United States. This hemoderivative, which will enter the market during 2007 under the name *Flebogamma® DIF*, will be manufactured in GRIFOLS' new IVIG production plant located in Parets del Vallés (Barcelona), which is also FDA certified. Grifols undertook an investment of 12 million euros between 2003 and 2005 to build the new plant, and the project as a whole has involved an investment of nearly 30 million euros.

Flebogamma<sup>®</sup> DIF (**double inactivation and filtration**) incorporates two distinct inactivation stages and is the only product on the market whose production process incorporates 20 nanometer nanofiltration adding to its proven safety profile.

In addition, the production process used to produce Flebogamma<sup>®</sup> DIF, the result of research carried out by Grifols, is more efficient and helps to significantly increase yield per liter of plasma used, allowing for more productive usage of raw materials in the medium term.

This new generation of IVIG exemplifies Grifols' commitment to providing the medical and hospital community with the best possible product, based on the constant efforts of its R&D team to find new processing methods and ways to adopt the latest technologies available in the industry.

In parallel with the registration of its new IVIG product in the United States, Grifols has begun registration procedures with European agencies and expects



to receive authorization during 2007 from the European Agency for the Evaluation of Medicinal Products (EMEA) to begin distribution in Europe.

During 2005, sales of Flebogamma® reached 160 million euros, achieving growth of 38% in comparison with the previous year. IVIG, albumin and factor VIII are three of the principal hemoderivatives produced by the group, generating 85% of Bioscience division sales in 2005.

## Making a good product better

The new *Flebogamma*® *DIF* is an evolutionary step in the development of a proven product. Grifols' first Flebogamma product, launched in 1993 in Germany, was perceived from the start as an innovative contribution, due to its safety and effectiveness. Since then it has enjoyed tremendous market acceptance, with 30 million grams having been sold in more than 30 countries and the product achieving sales leadership in Europe in 2003.

One of the main advantages introduced by Flebogamma® in 1993 was its liquid presentation, making a more convenient alternative to existing lyophilized products that took longer to prepare. In addition it could be kept at room temperature, thus eliminating the need for refrigeration.

## About Grifols

Grifols is a Spanish holding company specializing in the pharmaceuticalhospital industry, with a presence in more than 90 countries. It is the leading European company in the hemoderivative market, and the third largest producer in the world. In the coming years it will leverage its leadership position in the industry as a vertically integrated company, as a result of investments already undertaken: in terms of raw materials, it has assured an ongoing supply of plasma, and its fractioning capacity will allow it to meet growing market demand, principally in the United States where the company foresees a growing presence.