Grifols obtains EMEA authorization to distribute a new generation of IVIG in Europe

- The company plans to start selling in Europe in 2008.
- European approval obtained eight months after authorization by the FDA.

Barcelona, 27 August 2007. The European Medicines Agency (EMEA) has granted Grifols a licence to sell its new generation of Intravenous Immunoglobulin (IVIG) in all the country members of the European Union, under the name Flebogammadif®. This licence has been obtained only eight months after the Food & Drug Administration (FDA) authorized distribution of the same plasma product in the United States.

Grifols began distribution of the new generation of IVIG in the North American market in July 2007 under the name Flebogamma® DIF and aims to complete the transition from traditional Flebogamma® in this market by the end of the year. Gradual distribution of Flebogammadif® in European Union countries will begin in 2008, and will be rolled out to other markets.

Flebogammadif® (Double Inactivation and Filtration) is the only polyvalent IVIG on the market which incorporates two specific inactivation stages in its production process, together with nanofiltration at 20 nanometres, significantly increasing its safety margin.

In addition, the production process, which is the result of research carried out and patented by Grifols, is more efficient and significantly improves the yield per litre of plasma, ensuring more efficient use of the raw material over the medium term.

Flebogammadif® is manufactured at the Barcelona plant, which has a production capacity of 12 million grams per year. This will enable the group to increase its production levels as part of its growth plans.

Approval of this hemoderivative for the European market applies both to replacement therapy in primary and secondary immunodeficiencies, and to immunomodulation treatment in autoimmune diseases (idiopathic thrombocytopenic purpura, Guillain Barré syndrome and Kawasaki disease) and in allogeneic bone marrow transplantation.
About Grifols

Grifols is a holding company specialized in the hospital-pharmaceutical sector and is present in more than 90 countries. Since May 2006 it has been quoted on the Spanish Mercado Continuo and is included in the Spanish index of medium-sized capitalization companies (IBEX MEDIUM CAP). It is the leading European company in plasma derivatives and the fourth largest producer in the world. Recent investments mean that Grifols will continue to strengthen its leadership in this industry as a vertically integrated company. In terms of raw materials, the company has ensured its supply of plasma with 77 plasmapheresis centres in the United States, while its fractionation capacity with manufacturing facilities in Barcelona (Spain) and Los Angeles (United States) will allow it to meet growing market needs.