## **Investor Relations**



## Bayer HealthCare Division Biological Products:

## New Immune Globulin Intravenous Treatment for Approval in Key Global Markets Submitted

New product is based on breakthrough purification process

Leverkusen - Bayer HealthCare Division Biological Products (BP) announced today that it has submitted its next generation immune globulin intravenous (IGIV) product for regulatory approval in the United States, Canada and Germany. Submitted under the trade name Gamunex<sup>™</sup>, Bayer BP's new IGIV-C product introduces a breakthrough purification process, Caprylate/Chromatography, designed to establish new standards in product purity and supply reliability. Gamunex<sup>™</sup> is the first newly developed IGIV product to be submitted to the Food and Drug Administration (FDA) in over a decade.

"With the approval process underway in three key markets, there is growing anticipation about what's next in IGIV treatment," said Gunnar Riemann, Ph.D., executive vice president, Bayer Corporation, and president, Bayer Biological Products. Dr. Riemann added that Bayer BP is also working to submit Gamunex™ dossiers elsewhere in Europe and other areas of the world. Bayer BP currently manufactures and distributes Gamimune® N 10%/Polyglobin® 10%, Immune Globulin Intravenous (Human) 10%, which is approved for various conditions such as primary immune deficiency, idiopathic thrombocytopenic purpura, pediatric AIDS, and bone marrow transplants. In addition, it has also been approved in Europe for the treatment of Kawasaki's Disease, Guillain-Barré Syndrome and secondary immunodeficiency disorders.

To support the approval for Gamunex<sup>™</sup>, Bayer BP undertook an unprecedented licensure-relevant clinical trial program, including the largest-ever series of trials involving patients with primary immune deficiency. The clinical trial program consisted of seven trials worldwide, including more than 350 patients from leading medical centers. Of special importance were the powered and comparative (IGIV versus Gamimune<sup>®</sup> N) trials, which are expected to "demonstrate for the first time whether different production methods lead to different clinical outcomes," said Dr. Riemann, referring to Bayer's new state-of-the-art manufacturing facility in Clayton, North Carolina. The facility houses the new Caprylate/Chromatography

purification process – and is the only facility of its size exclusively dedicated to producing this biological product.

"The Immune Deficiency Foundation is pleased with Bayer's continued research and development into life-saving therapies that benefit our unique patient population," said Dr. Richard Barr, Chairman of the Board for the Immune Deficiency Foundation (IDF), in response to Bayer BP's recent submissions for Gamunex $^{\text{TM}}$ .

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## **Forward-Looking Statements**

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.