



Investor News

Biological Products Division:

Bayer HealthCare Signs Development Deal for Longer-Acting Kogenate[®]

Breakthrough liposome technology may allow
new treatment paradigm of once weekly dosing in hemophilia A

Leverkusen / November 22, 2004 – Bayer HealthCare, LLC., Biological Products (BP) division, announced today it has signed an exclusive, global technology license with Zilip-Pharma, located in Amsterdam, Netherlands, for the development and commercialization of a new, longer-acting Kogenate product - a product with the potential to shift current treatment paradigms in hemophilia and simplify the lives of thousands of patients around the world. The deal between Bayer and Zilip-Pharma involves the application of patented liposome technology developed by Zilip-Pharma and its affiliated companies over several years. Clinical results obtained by Zilip-Pharma suggest that a prolonged interval between bleeding episodes – one week or more – occurs when factor VIII attached to liposomes is administered to individuals with hemophilia A.

Upon achievement of key milestones, including successful clinical development and regulatory approvals in key regions, upfront and milestone payments from Bayer to Zilip-Pharma would total 100 million US-Dollar plus royalties from sales of the new product. The agreement covers applications of the liposome technology to the current Kogenate recombinant factor VIII molecule, as well as other factor VIII molecules, which could be developed by Bayer in the future.

“A product with the potential to be dosed once weekly would be a major step forward in hemophilia care, improving convenience of administration and helping people live the lives they choose,” said Joseph Akers, president, Bayer Biological Products. “Additionally, this is a major opportunity for us to significantly strengthen our marketplace position so we can continue providing the most advanced products, technologies, and services for the hemophilia community.”

Zilip's liposomal technology utilizes PEGylated liposomes free of biologicals, which have a longer half-life and have been used successfully with other approved products. Whereas conventional liposomes can sometimes be mistaken as foreign by the body's immune system, these liposomes represent a significant advance because they have a polyethylene glycol (PEG) coating that helps avoid detection by the immune system. The pilot clinical studies by the Zilip group suggest that Kogenate molecules attached to the surface of these liposomes can extend the interval between bleeding episodes requiring fewer treatments especially in prophylactic regimens.

“In our multi-center, patient-blinded phase II trial with severe hemophilia A patients, the time to next bleed following injection of PEGylated liposomal Kogenate was significantly prolonged. The results clearly show the potential for this treatment and we are very pleased that Bayer HealthCare's Biological Products Division will continue the development of the use of our technology within this area,” said Dr. Jack Spira, Medical Director of Zilip-Pharma.

Based on initial timelines for the project, Bayer and Zilip-Pharma hope that the next-generation Kogenate could be launched in five years, pending continued positive clinical results, required regulatory reviews, and necessary license approvals.

Approximately 400,000 people around the world have hemophilia. Hemophilia is an inherited bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. The disease is caused by deficient or defective blood coagulation proteins, known as factor VIII or IX. The most common form of the disease is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia B is characterized by deficient or defective factor IX.

Leverkusen, November 22, 2004

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Bayer HealthCare AG, a subgroup of Bayer AG with sales of approximately 8.9 billion Euro in 2003, is one of the world's leading, innovative companies in the health care and medical products industry.

The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diagnostics and Pharmaceuticals. 34,600 people are employed by Bayer HealthCare worldwide.

Our aim is to discover and manufacture innovative products that will improve human and animal health worldwide. Our products enhance well-being and quality of life by diagnosing, preventing and treating disease.

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.