Therapy of Hemophilia B

Bayer Signs Hemophilia Gene Therapy Deal with Avigen

Leaders in Gene Therapy and Hemophilia join Forces

Leverkusen, Germany, Alameda,USA — Bayer Corporation, a worldwide health care and life sciences company and leader in the development, manufacture, and distribution of hemophilia treatments, and Avigen, Inc., a biotechnology company at the forefront of new gene transfer therapies, announced today that they have taken an important step in the treatment of hemophilia B. The two companies signed an agreement that grants exclusive worldwide marketing and distribution rights to Bayer for Avigen's Coagulin-B™ gene therapy treatment for hemophilia B.

The deal, valued up to $ 60 million, includes a $15 million up-front purchase of Avigen stock, at a premium to market, milestone payments, and payment of the clinical trial and AAV vector manufacturing costs by Bayer. Additionally, Avigen will receive a substantial share of revenue from future Coagulin-B™ sales. Avigen will manufacture worldwide and produce the product at its new manufacturing facility in Alameda, Calif. The product's label will bear the names of both companies, Avigen as the manufacturer and Bayer as the distributor.

Coagulin-B™ is Avigen's proprietary AAV vector, which carries the gene for factor IX, the missing or deficient protein that causes hemophilia B. Coagulin-B™ is designed to deliver the factor IX gene into the patient's muscle cells where it will continuously produce factor IX. Sustained levels of factor IX in the bloodstream are expected to substantially reduce spontaneous bleeding episodes and the need for factor IX protein infusion. Avigen officials are optimistic that the continuing research will demonstrate promising results.

Under the terms of the agreement, Bayer, in collaboration with Avigen, will conduct the planned Phase II/III clinical trials for Coagulin-B™. In collaboration with Bayer, Avigen will file for regulatory approvals and will be the holder of regulatory licenses worldwide, including the United States, European Union, Canada, and Japan.

Hemophilia B is a sex-linked bleeding disorder caused by the absence or deficiency of the blood clotting protein factor IX. According to the World Hemophilia Foundation, one in 10,000 males born worldwide has hemophilia. The two major forms of the disease are hemophilia A and hemophilia B. The more common, hemophilia A, is caused by a lack of blood clotting protein factor VIII. Hemophilia B, the target of the current research, is about one-fifth as common as hemophilia A. Worldwide, the estimate of people suffering from hemophilia is 400,000.

“We are pleased to partner with Avigen in this effort because it represents an exciting leap forward for people with hemophilia,” said Jan Turek, senior vice president and general manager of Bayer Corporation’s Biological Products Business Unit Worldwide. “We are confident that Coagulin-B™ will be the first gene therapy application for the treatment of hemophilia. This is the kind of significant discovery the hemophilia community has been anxiously awaiting.”

“Avigen is pleased with the agreement on two levels,” said John Monahan, Ph.D., Avigen president and CEO. “First, in Bayer we have found a prestigious worldwide pharmaceutical company that is a leader in the hemophilia market, having worked to treat this disease for decades. Second, Bayer has the resources to conduct and finance worldwide clinical testing for Coagulin-B™ and has a strong worldwide marketing and distribution presence in hemophilia treatment. The Bayer-Avigen combination of expertise and resources will enhance our capability to deliver this product to market quickly so that patients can benefit from it. At the same time, the partnership will enable Avigen to focus its resources on other products in the development pipeline for the treatment of hemophilia A and other genetic disorders.”

“Gene transfer therapy shows promise in the treatment of hemophilia, and is an important medical breakthrough offering the potential for a cure,” continued Turek. “Avigen is on the cutting edge of technology for gene therapy products derived from adeno-associated virus (AAV), and we are excited about bringing

our expertise in clinical development to this partnership in order to move Coagulin-B™ to market as quickly as possible. This alliance reinforces our ongoing commitment to bleeding disorders, and serves as an example of how our substantial investments in research and development are making pioneering therapies a reality for the bleeding disorders community."

"The agreement advances our tradition of offering innovative, safe and effective therapies to individuals with hemophilia. Bayer has more than two decades of proven success in the hemophilia market including the recent launch of Kogenate® FS/KOGENATE® Bayer for the treatment of hemophilia A," added Turek. "At Bayer, it has been our mission, since the introduction of the first factor IX replacement product in 1969, to quickly make available new, safer, and more technologically advanced products to patients with bleeding disorders. Bayer will continue to explore new treatment options that can dramatically improve the quality of life of patients with hemophilia including gene therapy research in hemophilia A."

This AAV – vector based product builds on the foundation of pioneering research conducted at the Children's Hospital of Philadelphia (CHOP) and Stanford University by Dr. Katherine High and Dr. Mark Kay respectively. Numerous experiments in animals have shown the product to be extremely safe and capable of producing therapeutic levels of the missing Factor IX in animals. Phase I clinical studies are underway, being led by Dr Catherine Manno at CHOP. If the results observed in the animal studies are borne out in clinical trials, such levels in humans would result in significant reduction in bleeding episodes.

Based in the San Francisco Bay area, Avigen, Inc., is a biotechnology company involved in the development of gene therapy products derived from AAV for the treatment of inherited and acquired diseases. Avigen's proposed gene therapy products are designed for direct administration to patients in order to achieve production of therapeutic proteins within the body. Additional information on Avigen's proprietary gene therapies can be found at *www.avigen.com*.

Bayer Corporation is a research-based company with major businesses in health care, life sciences, and chemicals, with 1999 sales of $8.9 billion. The Bayer Biological Products Business Unit, headquartered in Research Triangle

Park, N.C., is responsible for the global development and marketing of Bayer's recombinant antihemophilic factor replacement products. Bayer currently provides nearly 50 percent of the world's supply of recombinant factor VIII for hemophilia A patients. Bayer recently made a significant advancement in the treatment of the hemophilia A with the launch of Kogenate®FS/ KOGENATE® Bayer , a next generation formulation recombinant factor VIII, which is formulated without human proteins. Recent and planned investments in research and development and manufacturing technology are expected to result in additional new products, enhanced safety profiles, and increased production capacity for products in chronically short supply.

Leverkusen, November 17, 2000