

Inspiration Biopharmaceuticals Announces Filing of IND for Novel Recombinant Factor IX Product, IB1001, for the Treatment of Hemophilia B

LAGUNA NIGUEL, Calif., Nov. 13 /PRNewswire/ -- Inspiration Biopharmaceuticals announced today that it has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to begin clinical trials with IB1001, an intravenous recombinant Factor IX (rFIX) product for the on demand and prophylactic treatment of the bleeding disorder associated with hemophilia B.

Upon FDA approval of the IND application, Inspiration Biopharmaceuticals intends to enter Phase 1/2 clinical trials to evaluate the pharmacokinetics (PK) and safety profile of IB1001, compared with the commercially available Factor IX products; rFIX, BeneFIX(R) and plasma-derived Factor, Mononine(R). Following successful completion of the PK phase of this study, patients will then enroll in one of two trials: a six month Phase 1/2 On Demand trial to document safety and efficacy in treating spontaneous bleeding episodes or a pivotal Phase 2/3 Prophylaxis trial to document safety and efficacy in the prevention of spontaneous bleeding. In addition, the safety and efficacy of peri-surgical prophylactic administration of IB1001 to control bleeding during surgical procedures will be evaluated. The rate of inhibitor formation will be evaluated throughout all phases of the clinical investigation of IB1001.

"We are excited to be filing an IND for IB1001," said Michael Griffith, Ph.D., President and CEO, Inspiration Biopharmaceuticals. "Preclinical studies have demonstrated the expected PK and safety profile for IB1001 when compared to the clinically proven commercial Factor IX products. Our cost-effective manufacturing platform for Factor IX positions Inspiration to expand the global supply of i.v. rFIX and to develop next generation products to facilitate prophylactic care of the hemophilia B patients worldwide. Our ultimate goal is to leverage our low cost manufacturing technology to find the means for non-invasive delivery of Factor IX which we believe may represent the equivalent of a therapeutic cure for patients suffering from this disease.

"Our vision is that one day all patients with hemophilia, regardless of where they live, will have access to treatment. More affordable treatment is critical to achieving treatment for all," stated Mark Skinner, President, World Federation of Hemophilia. "The availability of lower-cost rFIX products to treat hemophilia B could facilitate more prophylactic use, as well as make treatment more accessible to people worldwide."

About Hemophilia

Hemophilia is a lifelong, inherited bleeding disorder caused by low levels, or absence of a protein called a clotting factor, essential for blood clotting. This inability to clot results from an error in a person's genetic code, and occurs in approximately 1 in 10,000 male

births. It is estimated that over 400,000 people worldwide suffer from hemophilia, of which only 25% currently receive therapy. There are two types of hemophilia, hemophilia A and hemophilia B. Hemophilia A is caused by a lack of Factor VIII and hemophilia B is caused by a deficiency of Factor IX.

About Recombinant Protein Manufacturing Technology

Inspiration Biopharmaceuticals uses novel patent protected, recombinant protein manufacturing technologies, which significantly increase cell-line productivity. This in turn decreases manufacturing capacity requirements, and significantly lowers the overall production cost for Factor products compared with existing manufacturing processes. Inspiration believes that its technologies will allow introduction of patient friendly, cost-effective products, which will provide equal or enhanced potency compared to those currently available.

About Inspiration Biopharmaceuticals

Inspiration Biopharmaceuticals, founded in 2004, is developing treatments for hemophilia that have the potential to broaden patient access to therapy, including prophylactic use. Greater access and more frequent, prophylactic therapy have been shown to reduce complications of the disease and enhance patients' long-term health and quality of life.

Underlying the Company's programs is a novel, proprietary manufacturing technology that allows a greater yield of high-quality protein at a significantly lower cost than is currently available. Inspiration is utilizing this technology to develop a portfolio of hemophilia and bleeding disorder products that address a \$5 billion market worldwide.

Inspiration's lead product candidate, an intravenous recombinant Factor IX, has completed preclinical testing and is poised to enter Phase I/II clinical studies in the United States.

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