Inspiration Biopharmaceuticals Announces Clinical Hold of Clinical Trials Evaluating IB1001 for the Treatment and Prevention of Bleeding in Hemophilia B

Cambridge, Mass. (USA), July 10, 2012 – Inspiration Biopharmaceuticals, Inc. (Inspiration) today announced that the U.S. Food and Drug Administration (FDA) has notified the Company that the agency has placed a clinical hold on clinical trials evaluating the safety and efficacy of IB1001, an intravenous recombinant factor IX (rFIX) being investigated for the treatment and prevention of bleeding episodes in people with hemophilia B.

The clinical hold impacts two ongoing IB1001 clinical trials – a phase 3 study evaluating the safety and efficacy of IB1001 to treat and prevent bleeding episodes in adults with hemophilia B, and a phase 3/3b study evaluating the safety and efficacy of IB1001 to treat and prevent bleeding episodes in previously treated pediatric subjects with hemophilia B. The adult study has completed its primary analysis period.

Inspiration recently reported to the FDA that, during the course of routine laboratory evaluations conducted as part of an ongoing phase 3 clinical trial, the Company discovered that a higher proportion of individuals treated with IB1001 have developed antibodies to proteins from the Chinese hamster ovary, or CHO, host cells used to manufacture the therapy than was expected based on earlier study data. Inspiration has notified clinical sites in the U.S. to hold treatment of patients with IB1001. Inspiration is also sharing the FDA directive with regulators in countries outside of the U.S. where the studies are being conducted.

Small amounts of host cell protein are expected and documented in recombinant therapeutic products of all types. Nevertheless, the higher than expected rate of anti-CHO antibody development in people treated with IB1001 has led Inspiration to initiate a thorough investigation.

A total of 86 people with hemophilia B have received IB1001 in clinical studies and, to date, no adverse events related to the development of antibodies to CHO protein have been reported. Furthermore, no relationship has been observed between the development of anti-CHO protein reactivity and the development of any antibodies to factor IX. Inspiration continues to follow subjects enrolled in clinical trials of IB1001 to collect safety-related information and will share this information with regulators.

“As always, the safety of participants in our clinical programs is our primary concern. We are conducting a full investigation into the root cause of these antibodies,” said John P. Butler, Chief Executive Officer of Inspiration. “We have already made progress in identifying potential options to reduce antibody formation and will continue to work with the FDA on plans to move the IB1001 program forward. At Inspiration we are committed to developing the best possible treatment options for people with hemophilia, and this commitment drives our IB1001 program.”

About Inspiration Biopharmaceuticals

As the only biopharmaceutical company dedicated solely to hemophilia, Inspiration is committed to improving the care of people with this condition by broadening treatment choices, expanding global access to care, and advancing innovative therapies. Founded by two families whose sons have hemophilia, Inspiration is inspired to make a difference in the lives of people impacted by hemophilia around the world.

Inspiration's lead product candidates include IB1001 and OBI-1, a recombinant porcine factor VIII (FVIII) being investigated for the treatment of serious bleeds in patients with congenital hemophilia A with inhibitors or acquired hemophilia A.

For more information about Inspiration Biopharmaceuticals, please visit www.inspirationbio.com.

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