CSL Behring’s Long-acting rIX-FP
for Hemophilia B - IDELVION® - Receives Positive Opinion from European Medicines Agency CHMP

MARBURG, Germany – February 29, 2016 – Global biotherapeutics leader CSL Behring announced today that the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting marketing authorization for IDELVION® (Coagulation Factor IX (Recombinant), Albumin Fusion Protein) for patients with hemophilia B. IDELVION® is CSL Behring’s long-acting fusion protein, linking recombinant coagulation factor IX with recombinant albumin. IDELVION® was designated as an orphan medicinal product in 2010 by the European Commission.

“CHMP’s positive opinion for IDELVION® moves us one step closer to bringing this long-acting treatment option to hemophilia B patients in Europe,” said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. “Once approved, IDELVION® will provide hemophilia B patients in the European Union with a treatment option with prolonged dosing intervals up to 14 days. These intervals have been achieved while maintaining high levels of factor activity and very low annualized bleeding rates, delivering on our promise to develop and bring to market innovative specialty biotherapies that help patients live full lives.”

About Hemophilia B
Hemophilia B is a congenital bleeding disorder characterized by deficient or defective factor IX. Hemophilia B affects more than 10,000 people throughout Europe according to the European Haemophilia Consortium.

About PROLONG-9FP
The CHMP positive opinion is based on the PROLONG-9FP clinical development program. PROLONG-9FP includes Phase I through Phase III open-label, multicenter studies evaluating the safety and efficacy of IDELVION® in adults and children (ages 1 to 61 years) with hemophilia B (FIX ≤ 2%).
The data from PROLONG-9FP showed median annualized spontaneous bleeding rates (AsBR) of zero and factor IX activity levels above 5 percent in patients using IDELVION® prophylactically. According to the World Federation of Hemophilia, patients with factor IX activity levels above 5 percent are considered to have mild hemophilia. This result was achieved for both 14-day dosing and 7-day dosing. The data for on-demand therapy showed that 93.6 percent of bleeds were controlled with one infusion, while 98.6 percent were controlled with one or two infusions. The most common adverse reactions in clinical trials were injection site reactions and headache. Data from PROLONG-9FP were recently published in the American Society of Hematology’s publication Blood.

About IDELVION

CSL Behring engineered IDELVION® to extend the half-life of recombinant factor IX through fusion with recombinant albumin. CSL Behring selected recombinant albumin as its fusion partner for its coagulation factor proteins due to its long physiological half-life.

IDELVION® is approved in Canada and regulatory agencies in the U.S., Australia, Switzerland and Japan are also currently reviewing CSL Behring’s license applications for IDELVION®. For more information about CSL Behring's recombinant coagulation factor products in development to treat hemophilia, visit http://www.cslbehring.com/products/bleeding-disorders/novel-recombinant-hemophilia-treatments.

About CSL Behring

CSL Behring is a global biotherapeutics leader which is driven by its promise to save lives. Focused on serving patients’ needs by using the latest technologies, we develop and deliver innovative therapies that are used to treat coagulation disorders, primary immune deficiencies, hereditary angioedema, inherited respiratory disease, and neurological disorders. The company’s products are also used in cardiac surgery, organ transplantation, burn treatment and to prevent hemolytic disease of the newborn.

CSL Behring operates one of the world's largest plasma collection networks, CSL Plasma. The parent company, CSL Limited (ASX:CSL), headquartered in Melbourne, Australia, employs more than 16,000 people with operations in more than 30 countries.
For more information visit www.cslbehring.com and follow us on www.Twitter.com/CSLBehring.

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Media:
Greg Healy
CSL Behring
Office: 610-878-4841
Mobile: 610-906-4564
Email: Greg.Healy@cslbehring.com