European Commission Approves IDELVION® -- CSL Behring’s Novel Hemophilia B Treatment with Up to 14-day Dosing Intervals

- In clinical trials, IDELVION maintained factor IX activity levels above 5 percent over 14 days in the majority of patients, resulting in a median annualized spontaneous bleeding rate (AsBR) of zero.

- This long-acting recombinant albumin fusion protein for children and adults is CSL Behring’s first product from its innovative recombinant factor development program to receive European Commission approval.

- IDELVION is now approved in the European Union, United States and Canada.

MARBURG, Germany – May 11, 2016 – CSL Behring announced today that the European Commission has approved IDELVION® [albutrepenonacog alfa], its innovative, long-acting albumin fusion protein linking recombinant coagulation factor IX with recombinant albumin for the treatment and prophylaxis of bleeding in patients with hemophilia B (congenital factor IX deficiency). IDELVION can be used for all age groups (children and adults). The approved treatment regimen includes routine prophylaxis to prevent or reduce the frequency of bleeding episodes; on-demand control; and the perioperative management of bleeding (around the time of surgery).

IDELVION delivers high-level protection maintaining factor IX activity levels above 5 percent in most patients over 14-days. As a result, appropriate patients, age 12 and older, can go up to 14 days between infusions and achieve excellent bleeding control. This also reduces the monthly number of units needed for prophylaxis therapy.

“Offering 14-day dosing, IDELVION helps patients maintain higher factor IX levels over a long period of time, providing them with greater freedom from frequent infusions,” said Elena Santagostino, M.D., Ph.D., Professor in the Medical School of Clinical and Experimental Hematology at the University of Milan/IRCCS Maggiore Hospital, and lead investigator of the PROLONG-9FP clinical development program. “This is an important attribute for my patients who require a prophylactic regimen but don’t want treatment to disrupt their active lives.”

The approval of IDELVION is based on results from 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 children and adults (ages 1 to 61 years) with hemophilia B (factor IX levels ≤ 2%).

“IDELVION provides excellent bleeding control by maintaining factor IX activity levels above 5 percent over a prolonged period of time,” said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. “IDELVION delivers on CSL’s 100 year promise to develop and provide innovative specialty biotherapies that patients need and want. We look forward to bringing IDELVION to the European market and are particularly excited about the positive impact this long-acting therapy can have on the lives of patients with hemophilia B as we enter our next century.”

IDELVION will be launched in European markets in the coming months, as market access and pricing are obtained.

About Hemophilia B
Hemophilia B is a congenital bleeding disorder characterized by deficient or defective factor IX; nearly all affected patients are male. People with hemophilia B may experience prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. Hemophilia B affects more than 10,000 people throughout Europe according to the European Haemophilia Consortium.

About PROLONG-9FP
The data from PROLONG-9FP showed median annualized spontaneous bleeding rates (AsBR) of zero and factor IX activity levels above 5 percent in the majority of patients using IDELVION® prophylactically. According to the World Federation of Hemophilia, patients with factor IX activity levels above 5 percent (and below 50 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 94 percent of bleeds were controlled with one infusion, while 99 percent were controlled with one or two infusions. The most common adverse reaction in clinical trials was headache. Data from PROLONG-9FP were recently published in the American Society of Hematology’s publication Blood.

About IDELVION®
IDELVION®, albutrepenonacog alfa, is indicated in children and adults with hemophilia B (congenital factor IX deficiency) for the treatment and prophylaxis of bleeding.
The approved treatment regimen includes on-demand control and prevention of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. IDELVION is not indicated for induction of immune tolerance in patients with hemophilia B. IDELVION is contraindicated in patients who have had life-threatening hypersensitivity to the product or its components, including hamster proteins.

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. Additionally, recombinant albumin has been shown to have a good tolerability profile, low potential for immunogenic reactions and a well-known mechanism of clearance.

IDELVION® is also approved in the United States and Canada. Regulatory agencies in Australia, Switzerland and Japan are currently reviewing CSL Behring’s license applications for IDELVION.

The European Commission approved IDELVION as an orphan medicinal product -- intended for the safe and effective treatment, prevention or diagnosis of life-threatening or chronically debilitating rare disease that affect not more than 5 in 10,000 people throughout Europe. As an orphan medicinal product IDELVION has been granted market exclusivity for 10 years in the European Union.

For more information about CSL Behring's recombinant 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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