CSL Behring Receives EU Orphan Drug Designations for rVIIa-FP for Hemophilia A and B Treatment

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KING OF PRUSSIA, Pa., May 31, 2011 /PRNewswire/ -- **CSL Behring** [1] announced today that it has been granted Orphan Drug Designations (ODD) by the European Commission for the development of its recombinant fusion protein linking coagulation factor VIIa with albumin (rVIIa-FP), a novel therapy to treat hemophilia A and hemophilia B patients with inhibitors. The designations would entitle CSL Behring to exclusively market recombinant factor VIIa fused with albumin in Europe for a period of 10 years if the product at the stage of license application fulfils the orphan drug requirements. Based on the submission of data from the company's Pediatric Investigation Plan, once available, the 10-year market exclusivity may be extended to 12 years.

Under these designations European Medicines Agency (EMA) will also provide CSL Behring with development assistance and with reductions in certain regulatory fees.

"CSL Behring welcomes Orphan Drug Designation for rVIIa-FP as support of our ongoing commitment to developing, manufacturing and marketing products for the treatment of rare and serious diseases, such as hemophilia with inhibitors," said Val Romberg, Senior Vice President, Global Research & Development. "We will continue to work closely with the EMA to make this important therapy available to patients as soon as possible."

An orphan drug designation application has not yet been submitted in the United States.

By providing incentives to the pharmaceutical industry, the EU legislative framework for orphan medicines encourages the development of products intended to diagnose, prevent and treat life-threatening or chronically-debilitating conditions that impact up to 5 in 10,000 people in the European Union. The initiative helps improve access to quality medical care for patients who have rare diseases for which there are few, if any, approved treatments.

About Hemophilia

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