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Global biotherapeutics company CSL Behring has submitted its new drug application (NDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for its investigational fusion protein linking recombinant coagulation factor IX with recombinant albumin (rIX-FP).

rIX-FP is a long-acting recombinant albumin fusion protein for people with hemophilia B, a congenital bleeding disorder characterized by deficient or defective factor IX. Based on the 2011 National Survey of Coagulation Disorder, hemophilia B occurs in approximately 1 to 2 of every 100,000 male births in Japan.

"CSL was formed nearly 100 years ago with a promise to develop and deliver innovative specialty biotherapies that help people with serious medical conditions live full lives," said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited.

"rIX-FP demonstrates our longstanding commitment to innovation and patient care and we are pleased to submit our new drug application to PMDA. We look forward to, upon approval, bringing this innovative specialty biotherapy to patients with hemophilia B in Japan."

The submission 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 rIX-FP in adults and children (ages 1 to 61 years) with hemophilia B (FIX < 2%) who were previously treated with other factor IX products.