rIX-FP is an investigational, long-acting fusion protein linking recombinant coagulation factor IX with recombinant albumin; designed to preserve the native function of the coagulation factor in the fusion protein, while benefiting from recombinant albumin’s long physiological half-life.

Overview of Pivotal Phase III Clinical Trial Designs Evaluating the Safety and Efficacy of rIX-FP for Hemophilia B

rIX-FP in Previously-Treated Adults and Adolescents

- Assessed rIX-FP for prophylaxis treatment once every 7, 10 and 14 days and on-demand treatment of bleeding episodes in 63 previously-treated patients (12-61 years) (FIX activity ≤2% of normal).
- In one arm, 23 previously on-demand patients received only on-demand treatment for 6 months and switched to 7-day prophylaxis treatment; in the other arm, 40 patients received 7-day prophylaxis treatment for 6 months and then, if eligible, switched to a 10- or 14-day prophylaxis treatment interval for 12 to 18 months.
- Evaluated safety and efficacy of rIX-FP for prophylaxis treatment once every 7 days and treatment of bleeding episodes in 27 children (1-11 years); (FIX activity ≤2% of normal).
- Patients were treated for 12 months and/or 50 exposure days.

rIX-FP in Previously-Treated Children

rIX-FP in Previously-Treated Patients Undergoing Surgery

- Surgical sub-group analysis included in the Phase III studies as part of the global PROLONG-9FP clinical program.
- Evaluated rIX-FP to prevent bleeding during and post-surgery in 10 patients (8-51 years).