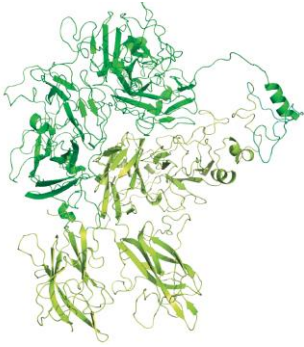


About rVIII-SingleChain

Novel Recombinant Single-Chain Factor VIII Construct



Depiction of rVIII-SingleChain Molecule

rVIII-SingleChain is a novel recombinant single-chain factor VIII (FVIII) construct specifically designed for greater molecular stability. It uses a covalent bond that forms one structural entity, a single chain, to improve the stability of FVIII and provide longer-lasting FVIII activity. It also has the potential for less frequent dosing – two to three infusions per week

Phase I/III Clinical Study Design

Open-label, multi-center study examining the efficacy and safety of rVIII-Single Chain. The data are part of the AFFINITY Phase I/III study that examined the safety, efficacy and pharmacokinetics of rVIII-SingleChain compared with recombinant human antihemophilic factor VIII (octocog alfa)

14,000+
exposure days

146 patients on prophylaxis (single infusion of 50 IU/kg of octocog alfa followed by a 4-day washout period; then, patients received a single infusion of 50 IU/kg rVIII-SingleChain to compare pharmacokinetics of both drugs

27 patients treated with rVIII-SingleChain on demand to prevent or treat bleeding episodes

Among the patients in the prophylaxis group, 32% were dosed twice-weekly and 54% received treatment three times per week

In total, 120 patients were treated for more than 50 days of exposure, and 52 had more than 100 days of exposure