About rVIII-SingleChain
Novel Recombinant Single-Chain Factor VIII Construct

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).

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.

Depiction of rVIII-SingleChain Molecule

14,000+ exposure days
146 patients on prophylaxis
27 patients treated with rVIII-SingleChain on demand to prevent or treat bleeding episodes

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