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Bayer initiates trial of new rFVIII to treat hemophilia A

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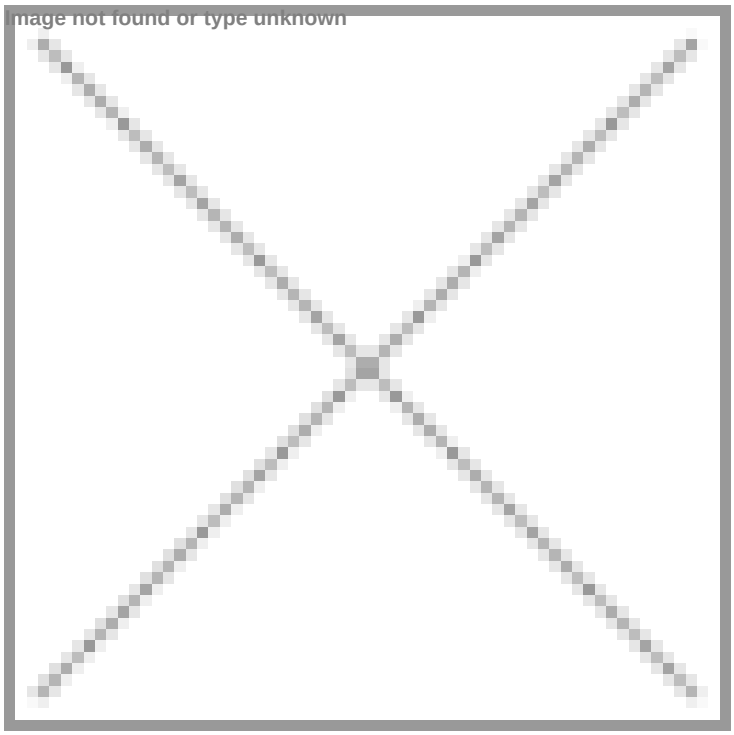

Singapore: Bayer HealthCare started enrolling patients in an international phase II/III trial called PROTECT VIII that is designed to evaluate its investigational compound BAY94-9027 for the treatment of hemophilia A.

The PROTECT VIII (prophylaxis in hemophilia A patients via directly pegylated long-acting rFVIII) trial will investigate whether the molecule, which is a recombinant human factor VIII (rFVIII), can prolong the duration of protection from bleeds and allow for less frequent infusions when used prophylactically, while also having the ability to treat acute bleeding events.

BAY94-9027 has been engineered to extend the half-life of rFVIII while preserving biologic activity by inserting a single cysteine (amino acid) site to its surface, which serves as an attachment site for a polyethylene glycol (PEG) polymer.

Dr Pamela Cyrus, VP and head, US medical affairs, Bayer HealthCare Pharmaceuticals, said that, "Bayer continues to invest in research that may provide innovative ways to advance patient care. This study is designed to determine the effects of a long-acting rFVIII product in people with hemophilia A."

PROTECT VIII is a multicenter, multinational, partially randomized, open-label trial evaluating the safety and efficacy of BAY94-9027 with different dosing frequencies in both prophylactic and on-demand treatment of bleeding in adults and adolescents with severe hemophilia A. The study will enroll 120 to 140 previously treated subjects (PTP) worldwide.