Xyntha®, Xyntha Solofuse® (antihemophilic factor [recombinant]) – New indication

- On August 13, 2020, the FDA approved Wyeth's Xyntha (antihemophilic factor [recombinant]) and Xyntha Solofuse (antihemophilic factor [recombinant]) for use in adults and children with hemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes.

- Xyntha is also approved for use in adults and children with hemophilia A (congenital factor VIII deficiency) for on-demand treatment and control of bleeding episodes and perioperative management.

- The approval of Xyntha for the new indication was based on 102 patients receiving Xyntha for routine prophylaxis, for comparison of annualized bleeding rate (ABR) to on-demand treatment alone as a part of 2 completed studies.

    — In patients ≥12 years, 42 (45%) reported no bleeding while on routine prophylaxis. The mean ABR for patients during routine prophylaxis was 88% lower than the mean ABR for patients during on-demand treatment.
    — In patients <12 years, 4 subjects (50%) reported no bleeding while on routine prophylaxis. The mean ABR for patients during routine prophylaxis was 97% lower than the mean ABR for patients during on-demand treatment.

- The recommended starting dose of Xyntha for the treatment of routine prophylaxis in adults and adolescents (≥ 12 years) is 30 IU/kg intravenously (IV) administered 3 times weekly.

- The recommended starting dose of Xyntha for the treatment of routine prophylaxis in children (< 12 years) is 25 IU/kg IV administered every other day. More frequent or higher doses may be required in children <12 years of age to account for the higher clearance in this age group.

- The dosing regimen (dose or frequency) should be adjusted based on the patient's clinical response.

    — Refer to the Xyntha drug label for dosing for all its other indications.