Adynovate® (antihemophilic factor [recombinant], PEGylated) – Expanded Indication

- On December 27, 2016, Shire announced the FDA approval of Adynovate (antihemophilic factor [recombinant], PEGylated) injection, for use in children and adults with hemophilia A (congenital factor VIII deficiency) for on-demand treatment of bleeding and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes.
    - Previously, Adynovate was only indicated for use in adolescents and adults (12 years and older) with hemophilia A, and was not approved for perioperative management.
    - Adynovate is not indicated for the treatment of von Willebrand disease.
- The approved expanded indication for Adynovate was based on an uncontrolled, open-label trial in 73 children under the age of 12.
    - Of those treated prophylactically, 38% experienced no bleeding episodes, 67% experienced no spontaneous bleeding episodes, and 73% experienced no joint bleeding episodes.
    - Moreover, control of bleeding was rated excellent or good in 90% of bleeding episodes. The median overall annualized bleeding rate among pediatric patients was similar to the rates seen in the adult study.
- The FDA also approved Adynovate for use in surgical settings for both pediatric and adult patients. The approval was based on interim trial results of an ongoing phase 3 study of perioperative control of hemostasis in 15 patients with severe hemophilia undergoing different surgical procedures.
    - Perioperative hemostatic efficacy was rated as excellent (blood loss less than or equal to that expected for the same type of procedure performed in a non-hemophilic patient, and required blood components for transfusions less than or similar to that expected in non-hemophilic population) for all 15 procedures.
- Adynovate is administered intravenously. The dosage and duration of treatment depend on the severity of factor VIII deficiency, the location and extent of the bleeding, and the patient's clinical condition. For complete dosing information, please refer to the drug label.