## Cuvitru™ (immune globulin subcutaneous [human], 20% solution) – New Drug Approval

- On September 14, 2016, Shire announced the FDA approval of Cuvitru (immune globulin subcutaneous [human], 20% solution), indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥ 2 years of age.
    - This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- PI is a group of > 300 genetic disorders in which part of the body's immune system is missing or functions improperly. It affects up to 6 million people worldwide.
- Cuvitru provides antibody replacement therapy to reduce the number and severity of infections seen in patients with PI. Cuvitru is a highly concentrated immune globulin solution that allows for decreased infusion duration and the number of infusion sites.
- The safety, efficacy, tolerability and pharmacokinetics of Cuvitru were evaluated in an open-label study of 74 patients with PI.
    - The rate of validated serious bacterial infections was 0.012 event/patient-year ($p < 0.0001$ compared with the historical control).
    - No related serious adverse event (AE) occurred during Cuvitru treatment. Related non-serious AEs occurred at a rate of 0.036 event/infusion.
    - The incidence of related local AEs was 0.015 event/infusion and of related systemic AEs was 0.021 event/infusion.
- Cuvitru is contraindicated in patients with anaphylactic or severe systemic hypersensitivity reactions to subcutaneous administration of immune globulin (human) and in IgA deficient patients with antibodies against IgA and a history of hypersensitivity.
- Similar to other immune globulin products, Cuvitru carries a boxed warning regarding thrombosis.
- Other warnings and precautions of Cuvitru include renal dysfunction/failure, aseptic meningitis syndrome, hemolysis, transfusion-related acute lung injury, transmissible infectious agents, monitoring laboratory tests, and interference with laboratory tests.
- The most common AEs (≥ 5%) with Cuvitru use were local adverse reactions, systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.
- Cuvitru is given subcutaneously. The recommended dose should be:
    - Calculated based on recommendations in the package label.
    - Administered at regular intervals from daily up to every two weeks (biweekly).
    - Individualized based on the patient's pharmacokinetic and clinical response.
    - Adjusted based on serum IgG trough levels.

Continued . . .

- Shire plans to launch Cuvitru in the coming weeks. Cuvitru will be available as a 200 mg/mL (20%) protein solution for subcutaneous infusion.