Asceniv™ (immune globulin intravenous, human – slra) – New drug approval

- On April 1, 2019, ADMA Biologics announced the FDA approval of Asceniv (immune globulin intravenous, human – slra), for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age).
    - PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- The efficacy of Asceniv was evaluated in an open-label, single-arm study in 59 adult and pediatric patients with PI. Patients received an Asceniv infusion administered every 3 or 4 weeks for 12 months. The study assessed efficacy in preventing serious bacterial infections, defined as a rate of < 1.0 cases of bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral abscess, and bacterial meningitis per person-year.
    - During the 12-month study period, zero serious acute bacterial infections occurred.
- Asceniv carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.
- Asceniv is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and IgA-deficiency patients with antibodies to IgA and a history of hypersensitivity.
- Additional warnings and precautions of Asceniv include hypersensitivity; hyperproteinemia, increased serum viscosity, and hyponatremia; aseptic meningitis syndrome; hemolysis; transfusion-related acute lung injury; transmissible infectious agents; monitoring laboratory tests; and interference with laboratory tests.
- The most common adverse reactions (≥ 5%) with Asceniv use were headache, sinusitis, diarrhea, viral gastroenteritis, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea.
- The recommended dose of Asceniv for replacement therapy in PI is 300 to 800 mg/kg body weight administered intravenously every 3 to 4 weeks. The dose may be adjusted over time to achieve the desired trough levels and clinical response.
    - For additional dosing and administration recommendations, refer to the Asceniv drug label.
- ADMA Biologics plans to launch Asceniv during the second half of 2019. Asceniv will be available as a liquid solution containing 10% IgG (100 mg/mL) for intravenous infusion.