Alyglo™ (immune globulin intravenous, human-stwk) – New drug approval

- On December 17, 2023, GC Biopharma announced the FDA approval of Alyglo (immune globulin intravenous, human-stwk), for the treatment of primary humoral immunodeficiency (PI) in adults.
    - This 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 immunodeficiency.
- Alyglo is a liquid solution containing immunoglobulin G (IgG) manufactured from pooled human plasma from U.S. donors.
- The efficacy of Alyglo was established in a prospective, open-label, single-arm study in 33 adult and pediatric patients with PI. Prior to enrollment, all patients were receiving stable doses of IV IgG replacement therapy. The primary efficacy analysis was annualized rate of acute serious bacterial infections (SBIs), defined as bacterial pneumonia, bacteremia/sepsis, bacterial meningitis, visceral abscess, and osteomyelitis/septic arthritis per patient per year.
    - During the 12-month study period, the acute SBI rate was 0.03 (with an upper one-sided 99% confidence limit: 0.31), which met the predefined success rate of less than one acute SBI per patient per year.
- Alyglo carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.
- Alyglo is contraindicated in:
    - Patients who have a history of anaphylactic or severe systemic reaction to the administration of human immune globulin
    - IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.
- Additional warnings and precautions for Alyglo 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 Alyglo use were headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.
- Alyglo is administered intravenously. Significant differences in the half-life of IgG among patients with PI may necessitate the dose and frequency of immunoglobulin therapy to vary from patient to patient.

Dose	Infusion number	Initial infusion rate	Maintenance infusion rate
300 – 800 mg/kg body weight every 21 or 28 days	For the 1st infusion	1 mg/kg/min (0.01 mL/kg/min)	Double the infusion rate every 30 minutes (if tolerated) up to 8 mg/kg/min (0.08 mL/kg/min)

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300 – 800 mg/kg body weight every 21 or 28 days	From the 2nd infusion	2 mg/kg/min (0.02 mL/kg/min)	Double the infusion rate every 15 minutes (if tolerated) up to 8 mg/kg/min (0.08 mL/kg/min)

- GC Biopharma's launch plans for Alyglo are pending. Alyglo will be available as a liquid solution containing 10% IgG (100 mg/mL).