Gammaplex® (immune globulin intravenous [human], 5% liquid) — Expanded Indication

• On August 6, 2015, Bio Products Laboratory announced the FDA approval of Gammaplex (immune globulin intravenous [human], 5% liquid) for the treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
  — Previously, Gammaplex was approved for the treatment of PI in adults.

• Gammaplex is also approved for the treatment of chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

• Primary immunodeficiencies are a group of immune disorders that can negatively impact the body’s ability to fight infection. In some primary immunodeficiencies, the immune system does not manufacture adequate quantities of antibodies such as immune globulin G.

• The expanded indication for Gammaplex is based on a 12-month open-label trial involving 25 children and adolescents aged 3 to 16 years. The efficacy analysis was based on the annual rate of serious acute bacterial infections (SABIs), defined as pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral abscess, and bacterial meningitis, per subject per year.
  — During the 12-month trial period, two SABIs occurred, with a mean event rate of 0.09 per year (upper 1-sided 99% CI: 0.36).

• Gammaplex carries a boxed warning regarding the risk of thrombosis, renal dysfunction and acute renal failure.

• The recommended intravenous (IV) dose of Gammaplex for PI in both adults and pediatric patients is 300-800 mg/kg (6-16 mL/kg) every 3 to 4 weeks.
  — The dosage should be adjusted over time to achieve the desired serum trough levels and clinical response.

• The recommended IV dose of Gammaplex for patients with ITP is 1 g/kg (20 mL/kg) on 2 consecutive days, providing a total dose of 2 g/kg.