**Introduction**

PlasmaCap IG is a 10% liquid formulation intravenous immune globulin (IVIG) product manufactured from US source plasma. The product is indicated for replacement therapy in primary immune deficiency diseases (PIDD) in patients two years of age and older. The clinical trial was initiated in 2017 in both the United States and Canada. The purpose of this study is to investigate the efficacy, safety, tolerability, and pharmacokinetics profile of PlasmaCap IG.

The adult portion of the trial was completed in February 2019 and the pediatric portion is expected to be completed in November 2020. Presented here is unofficial data. PlasmaCap IG is the first plasma derived product manufactured using PlasmaCap EBA technology.

PlasmaCap IG uses expanded bed adsorption (EBA) chromatography to selectively capture proteins in their native state, and in many cases, at a higher yield per liter of plasma (compared to published industry norms using traditional cold ethanol fractionation). PlasmaCap EBA selectively captures target proteins, and does not involve precipitation, potentially resulting in more consistent quality and purity when compared to conventional fractionation methods. The process does not use ethanol pre-treatment, and processing steps are performed at room temperature without the freeze/thaw of intermediate product fractions. These processing steps are performed under conditions which conserve the molecular structure of IgG.

Capture of native IgG from plasma is made possible by creating a stable fluidized bed that is not affected by the variability of optimal binding of IgG.

**Clinical Trial Methods**

**Clinical Trial Identifier #NCT03238079**

PlasmaCap IG is manufactured using a novel protein extraction method. Chromatography columns work through 3 major steps, Equilibration, Loading and Elution (Figure 3).

PlasmaCap EBA technology uses expanded bed adsorption (EBA) chromatography to selectively capture proteins in their native state, and in many cases, at a higher yield per liter of plasma (compared to published industry norms using traditional cold ethanol fractionation). PlasmaCap EBA selectively captures target proteins, and does not involve precipitation, potentially resulting in more consistent quality and purity when compared to conventional fractionation methods. The process does not use ethanol pre-treatment, and processing steps are performed at room temperature without the freeze/thaw of intermediate product fractions. These processing steps are performed under conditions which conserve the molecular structure of IgG.

The chromatography column works through 3 major steps, Equilibration, Loading and Elution (Figure 1-3).

**Figure 1.** EBA columns are expanded by flowing liquid upward through the column and equilibrated to condition the ligand for optimal binding of IgG.

**Figure 2.** IG molecules are unbound from the column, flowing upwards from the flow of elution buffer.

**Figure 3.** A tangential-carboxyl agrose beads with 6-aminobenzoic acid ligands selectively bind the Fc portion of IgG by isoelectric attraction, hydrogen binding, van der waals forces, in stacking, cation, aromatic ring, and hydrophilic interactions.

**Study Outcome Measures**

**Efficacy:**
- Primary: Mean annual acute serious bacterial infections (SABIs) is significantly less than 1/subject/year.
- Secondary:
  - Average serum IgG trough concentration prior to each infusion
  - Number of infection episodes (serious and non-serious)
  - Number of days missed of work/school/daycare or, use of antibiotics to treat infection and short-term prophylaxis prior to and following surgical and dental procedures
  - Ability of the Investigational Medicinal Product to maintain stable, therapeutic IgG levels

**Safety:** Adverse Event (AE), and safety, monitor for hemolysis and thromboembolic events.

**Pharmacokinetics:** Determine the PK profile plasma concentration-time curve and half life (t\(\text{1/2}\)) for each phase of the curve.

**Results**

**Adults**

- **Clinical Trial Methods**
  - **Diagnosis**
    - **Gender**
      - Male
      - Female
    - **Age**
      - 12-
      - 18-
      - 42 Adults
    - **Weight**
      - 39kg
      - 495mg/kg
      - 70kg
      - 73kg
      - 132kg
    - **Height**
      - 20.5
      - 5’
      - 16
      - 17
      - 11
      - 4
    - **Dose/Infusion**
      - 20.5
      - 371
      - 21
      - 1933
    - **Cmax**
      - 99.5 ± 0.3%
      - 68.7 ± 2.5
    - **AUC(0-t)**
      - 1933  (869)
    - **CL**
      - 42 Adults
    - **t1/2**
      - 11.4  (8.9)
    - **N=59**

**Children**

- **Clinical Trial Methods**
  - **Diagnosis**
    - Gender
    - Age
    - Weight
  - **PK Parameter**
    - **Dose/Infusion**
      - 30 mg
      - 99.5 ± 0.3%
      - 68.7 ± 2.5
    - **CL**
      - 42 Adults
    - **t1/2**
      - 11.4  (8.9)

**Discussion/Conclusions**

This preliminary data for adults and ongoing data for children, appear to indicate that PlasmaCap IG is efficacious, safe, and well tolerated in the treatment of patients with PIDD with no SABIs or related SAEs to date.

**References**