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**Control/Tracking Number:** 11-A-4143-AAAAI

**Activity:** Abstract

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**Pharmacokinetic Analysis (PK) of Immune Globulin Subcutaneous (Human), 10% (IGSC) Administered Intravenously or Subcutaneously in Subjects with Primary Immunodeficiency Diseases (PID)**

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*Abstract:*

**RATIONALE:** To compare total IgG area under the curve (AUC) following IV and SC administration, with the aim to show pharmacokinetics (PK) equivalence of a new 10% IGSC product.

**METHODS:** A multi-center, prospective, open label study evaluated pharmacokinetics, efficacy, and safety of IGSC 10% given IV and SC to subjects with PID. The dose of IGSC was adjusted during the study to obtain AUC<sub>SC</sub> that was comparable to the AUC<sub>IV</sub>. Bioavailability was evaluated as IgG-AUC for subjects ≥ 12 years old and as IgG trough levels for subjects age 2 to < 12 years old. IgG trough level assessments were used to individualize dosing.

**RESULTS:** A dose adjustment factor of 137% was determined to obtain equivalent AUC<sub>IV</sub> and AUC<sub>SC</sub>. The target serum IgG trough level on weekly IGSC treatment was 1.28 times (range: 1.13 - 1.43) the last IGIV trough level. Median IgG trough levels at the end of the study were 1250 mg/dL.

**CONCLUSION:** IGSC therapy at a dosing factor of 1.37 resulted in equivalent bioavailability to IV administration. This adjustment factor was similar to that found in a study with a 16% SC product, but was lower than the adjustment factor found in a study with a 20% SC product (1.52). The trough levels achieved were above the suggested protective range.

**Author Disclosure Information:** **H. Leibl:** Employee, Baxter BioScience. **R.L. Wasserman:** DallasAllergyImmunology, Physician, CSLBehring, GSK, Consultant, Speaker, Baxter Healthcare, Talecris, Consultant, CSLBehring, Baxter Healthcare, Talecris, Octapharma, Nabi, GSK, Medimmune, TEVA., Principle investigator, George, Hartz & Lundeen, Expert witness, AAAAI, Board of Directors. **I. Melamed:** IMMUNOe, President, Grifols Educational Grant, Baxter Educational Grant, Grant, CSL Behring, Pfizer, Teva, Baxter, Octapharm, GSK, Novartis, MedImmune, Ception, Principle investigator. **M. Stein:** Allergy Associates of the Palm Beaches, President, CSL Behring, Speaker, CSL Behring, Baxter Healthcare Corp, Bio Product Laboratory, Biotest Pharmaceuticals Corp., Investigator. **W. Engl:** Baxter BioScience, Employee. **R.I. Schiff:** Baxter BioScience, Employee. **D. Gelmont:** Baxter BioScience, Employee. **W.J. Grossman:** Baxter BioScience, Employee.

**Category (Complete):** 306. Immunodeficiency

**Keyword (Complete):** Immunodeficiency: Primary ; Immunoglobulin: Administration ; Immunoglobulins

**Presentation Preference (Complete):** No Preference

**Funding (Complete):**

**Primary Funding :** Industry

**If funded through university monies, grant monies or industry, please provide name of funding institution or company. :**

Baxter BioScience

**How many years experience in the field of, allergy, asthma, and immunology do you have? :** 30

**Which category best applies to the primary author?:** N/A

**Is there a Protocol Number or Clinical Trial Number assigned to this study?:** Yes

**Clinical Trial Number :** NCT00546871

**:** Yes

**\*:** Yes

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