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Efficacy Analysis 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 evaluate the efficacy of a new IGSC 10% preparation in terms of rate of infections and protective specific antibody titers.

METHODS: A multi-center, prospective, open label study evaluated efficacy, tolerability and pharmacokinetics of IGSC, 10% given IV or SC to 49 PID subjects. Efficacy was determined as the number of acute serious bacterial infections (ASBI) per subject year, and the overall incidence of infections and protective specific antibody titers.

RESULTS: The rate of ASBI was 0.067 per subject per year, with an upper confidence limit of 0.134, well below the established limit of 1 ASBI per subject per year. There were 3 episodes of acute serious bacterial pneumonia, none of which required hospitalization. The annualized rate of all infections during SC phase of the study was 4.1 infections/subject (95% CI 3.2-5.1). SC infusions were distributed almost evenly over the seasons. Trough levels of specific antibody to H. Influenza, Hepatitis B surface antigen and tetanus were in the protective range for all subjects during both IV and SC therapy, with titers substantially higher during the SC phase of the study for all three specific antibodies.

CONCLUSIONS: Efficacy of IGSC 10% replacement therapy was confirmed by rates of infection which are comparable to other SCIG and IVIG products. These data support application for approval of IGSC 10% as a therapy for patients with PID.

Author Disclosure Information: R.I. Schiff: Baxter BioScience, Employee. 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. H. Leibl: 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

Payment (Complete): Your credit card order has been processed on Tuesday 14 September 2010 at 4:14 PM.

Status: Complete

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