This clinical study synopsis is provided for informational purposes only. It may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained across the entire product development.
SYNOPSIS

<table>
<thead>
<tr>
<th>Name of Sponsor/Company:</th>
<th>Baxalta US Inc.(^i) and Baxalta Innovations GmbH(^ii)</th>
</tr>
</thead>
</table>
| Name of Investigational Product (IP) | 1. Immune Globulin Subcutaneous (Human) (IGSC, 20%)  
2. Gammagard Liquid (Kiovig, IGIV, 10%) |
| Name(s) of Active Ingredient(s) | 1. Immune Globulin Subcutaneous (Human) (IGSC, 20%)  
2. Immune Globulin Infusion (Human), 10% |

CLINICAL CONDITION(S)/INDICATION(S)

- Primary Immunodeficiency Diseases (PIDD)

PROTOCOL IDENTIFIER 170904

PROTOCOL TITLE A clinical study of immune globulin subcutaneous (Human), 20% solution (IGSC, 20%) for the evaluation of efficacy, safety, tolerability, and pharmacokinetics in subjects with primary immunodeficiency diseases

Short Title Ph 2/3 Study of IGSC, 20% in PIDD

STUDY PHASE Ph2/3

INVESTIGATORS AND STUDY SITES THAT ENROLLED SUBJECTS:

- MD, USA
- MD, USA
- MD, USA
- MD, PhD, USA
- MD, MD, USA
- MD, USA
- MD, USA
- MD, USA
- MD, PhD, USA
- MD PhD, USA
- MD, USA
- MD, Canada
- MD, USA
- MD, USA

\(^i\) Formerly Baxter Healthcare Corporation
\(^ii\) Formerly Baxter Innovations GmbH
PUBLICATION (REFERENCE): Based on interim data from Study 170904, a total of 2 abstracts have been published in 2014iii and 2015iv, respectively.

STUDY PERIOD

<table>
<thead>
<tr>
<th>Initiation</th>
<th>2013 JAN 28 (first subject in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Completion</td>
<td>2015 MAR 13 (last subject out)</td>
</tr>
<tr>
<td>Duration</td>
<td>approximately 26 months</td>
</tr>
</tbody>
</table>

STUDY OBJECTIVES AND PURPOSE

Study Purpose

- To develop a 20% SC immunoglobulin preparation for the treatment of patients with PIDD

Primary Objective

- To evaluate the efficacy of IGSC, 20% in preventing the development of acute serious bacterial infections in subjects with PIDD

Secondary Objective(s)

- To evaluate further efficacy assessments as well as the safety, tolerability, and PK characteristics of IGSC 20% in subjects with PIDD and assess quality of life and treatment satisfaction

Tertiary Objective(s)

None

STUDY DESIGN

<table>
<thead>
<tr>
<th>Study Type/ Classification/ Discipline</th>
<th>Efficacy, Safety, Pharmacokinetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Type</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Study Indication Type</td>
<td>Treatment</td>
</tr>
<tr>
<td>Intervention model</td>
<td>Non-randomized</td>
</tr>
<tr>
<td>Blinding/Masking</td>
<td>Open-label</td>
</tr>
</tbody>
</table>
| Study Design                          | This was a phase 2/3, prospective, open-label, non-controlled, multicenter, global study to evaluate efficacy, safety, tolerability, and PK of IGSC, 20%. This study was planned for approximately 70 subjects with PIDD, at least 2 years of age at the time of screening in the USA, Australia and Canada. The study consisted of 4 epochs as follows:  
  - **Epoch 1** subjects received IGI, 10% intravenously (IGIV, 10%). All subjects aged ≥12 years completed a PK assessment. |


- **Epoch 2**, subjects received IGSC, 20% subcutaneously at a dose adjusted to 145% of the IV dose. The first 15 subjects aged ≥12 years completed a PK assessment. Based on the PK data from Epoch 1 and Epoch 2, the IGSC, 20% dose that would, on average, provide equivalent IgG exposure as IGIV, 10% administration (“Adjusted Dose”) was assessed and was estimated to be 145 % of the IGIV, 10% dose.

- **Epoch 3**, subjects were treated with IGSC, 20% for 3 months at the “Adjusted Dose”. Since this Adjusted Dose represented the average dose-response of only 15 subjects, the possibility that some subjects could be over- or under-dosed, could not be excluded. Thus, for each subject an “Individually Adapted Dose” of IGSC, 20% was determined by comparing the trough level attained in Epoch 3 to the expected trough level calculated from the PK comparison of Epochs 1 and 2.

- **Epoch 4**, subjects were infused with IGSC, 20% at the “Individually Adapted Dose”.

Efficacy, safety and tolerability of IGSC, 20% were determined throughout Epochs 2 to 4 (up to 12 months). Treatment in Epoch 3 started as soon as the Adjusted Dose became available. Consequently, subjects who completed Epoch 1 after the Adjusted Dose was available omitted Epoch 2 and went directly into treatment with the Adjusted Dose (Epoch 3).

**CRITERIA FOR EVALUATION**

**Efficacy:**

**Primary Efficacy Outcome:**
Rate of validated acute serious bacterial infection (validated ASBI) defined as the mean number of validated ASBIs per subject per year in the intent-to-treat population. ASBIs included bacteremia/sepsis, bacterial meningitis, osteomyelitis/septic arthritis, bacterial pneumonia, and visceral abscess that were caused by a recognized bacterial pathogen.

**Secondary Efficacy Outcomes:**
1. Annual rate of all infections per subject
2. Annual rate of sinus infections per subject
3. Annual rate of fever episodes per subject
4. Annual rate of days off school/work or days unable to perform normal daily activities due to illness or infection per subject.
5. Annual rate of days on antibiotics per subject
6. Annual rate of hospitalizations for illness or infection per subject
7. Annual rate of days of hospitalizations for illness or infection per subject
8. Annual rate of acute (urgent or unscheduled) physician visits, or visits to the Emergency Room for illness or infection per subject.
Pharmacokinetics:

1. Bioavailability of IGSC, 20% as measured by the ratio of IgG AUC_{SC} (Epoch 4) to IgG AUC_{IV, 0-τ} (Epoch 1) adjusted for dose and dosing frequency (for subjects aged 12 and older)

2. Trough levels of IgG (total), IgG subclasses, and specific antibodies to clinically relevant pathogens (e.g. Clostridium tetani toxoid, Haemophilus influenzae type b, and Hepatitis B Virus)

3. Other pharmacokinetics parameters for IgG (total) and one specific antibody (anti- Haemophilus influenzae type b): for subjects 12 years of age or older included area under the curve over a dosing interval (AUC_{0-τ}), clearance (CL; for IV treatment) or apparent clearance (CL/F; for SC treatment), bioavailability (F), maximum observed concentration (C_{max}), minimum observed concentration (C_{min}), time to C_{max} (T_{max}) and T_{1/2} (for IV only).

For Children 2 to < 12 years, included for SC treatment in Epoch 4 area under the curve over a dosing interval (AUC_{0-τ}), apparent clearance (CL/F), maximum observed concentration (C_{max}) and minimum observed concentration (C_{min}).

4. The dose in Epoch 3 expressed as a percentage of weekly IV dose to achieve equivalent AUC, and the expected trough level increase at this dose obtained from PK data in Epochs 1 and 2, and a nomogram or table derived from this data to be used to determine the “Individually Adapted Dose” in Epoch 4 (Interim Analysis only).

Safety:

1. Related SAEs and Related AEs
   a. Number of SAEs and AEs (including and excluding infections) deemed related to the investigational product(s), divided by the number of subjects
   b. Number of SAEs and AEs (including and excluding infections) deemed related to the investigational product(s) divided by the number of infusions

2. All SAEs and AEs
   a. Number of SAEs and AEs (including and excluding infections) regardless of relationship to the investigational product(s) divided by the number of subjects
   b. Number of SAEs and AEs (including and excluding infections) regardless of relationship to the investigational product(s) divided by the number of infusions

3. Temporally Associated AEs
   a. Number of AEs (including and excluding infections) that began during or within 72 hours of completion of infusion divided by the number of subjects
   b. Number of AEs (including and excluding infections) that began during or within 72 hours of completion of infusion divided by the number of infusions
   c. Number of AEs (including and excluding infections) that began during or within 24 hours of completion of infusion divided by the number of subjects
   d. Number of AEs (including and excluding infections) that began during or within 24 hours of completion of infusion divided by the number of infusions
   e. Number of AEs (including and excluding infections) that began during or within 1 hour of completion of infusion divided by the number of subjects
<table>
<thead>
<tr>
<th>Number of AEs (including and excluding infections) that began during or within 1 hour of completion of infusion divided by the number of infusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Causally related and/or temporally associated AEs</td>
</tr>
<tr>
<td>The total number of all AEs (including and excluding infections) that began during infusion or within 72 hours of completion of an infusion (“temporally associated”) plus the total number of AEs (including and excluding infections) starting more than 72 hours following the completion of an infusion determined by the investigator to be at least possibly related to the study drug (“related”), divided by the total number of infusions</td>
</tr>
<tr>
<td>5. Local AEs</td>
</tr>
<tr>
<td>a. Proportion of infusions associated with one or more local AEs (including and excluding infections)</td>
</tr>
<tr>
<td>b. Proportion of subjects reporting one or more local AEs (including and excluding infections)</td>
</tr>
<tr>
<td>6. Infusion Tolerability</td>
</tr>
<tr>
<td>a. Proportion of infusions for which the infusion rate was reduced and/or the infusion was interrupted or stopped due to tolerability concerns or AEs</td>
</tr>
<tr>
<td>b. Proportion of subjects for whom the infusion rate was reduced and/or the infusion was interrupted or stopped due to tolerability concerns or AEs</td>
</tr>
<tr>
<td>c. Proportion of infusions tolerated with IV or SC administration</td>
</tr>
<tr>
<td>7. Short term tolerance. Changes graded according to Toxicity Table for:</td>
</tr>
<tr>
<td>a. Blood pressure</td>
</tr>
<tr>
<td>b. Heart rate (pulse)</td>
</tr>
<tr>
<td>c. Respiratory rate</td>
</tr>
<tr>
<td>d. Body temperature</td>
</tr>
<tr>
<td>8. Incidence of laboratory confirmed hemolysis that occurs following investigational product administration</td>
</tr>
</tbody>
</table>

**Quality of life/ Satisfaction:**

1. Quality of Life |
| a. Pediatric Quality of Life InventoryTM (PEDS-QLTM) (observer: parent) for the age group 2 to 4 and 5 to 7 years |
| b. PEDS-QLTM (observer: subject) for the age group 8 to 12, and 13 years (use 13 to 18 years form) |
| c. Short-Form 36v2 (SF-36v2) for the age group 14 years and older |

2. Life Quality Index |
| a. Life Quality Index (LQI); for the age group 2 to 12 years the observer was a parent, for the age group 13 years and older the observer was the subject |
| b. Treatment Satisfaction |
| Treatment Satisfaction Questionnaire for Medication (TSQM); for the age group 2 to 12 years the observer was a parent, for the age group 13 years and older the observer was the subject |
**Exploratory Endpoints:**

1. **Dose Corrections**
   a. Number and proportion of subjects for whom the immunoglobulin dose had to be changed due to:
      i. Increased incidence of illness/infection,
      ii. IgG trough level 500 mg/dL or below, or
      iii. Other medical indication.

2. **Optional Photo Recording of Infusion Procedure**

**INVESTIGATIONAL PRODUCT(S), DOSE AND MODE OF ADMINISTRATION, AND BATCH NUMBER**

<table>
<thead>
<tr>
<th>Investigational Product(s)</th>
<th>1. IGIV, 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage form:</strong></td>
<td>Injection, solution</td>
</tr>
<tr>
<td><strong>Dosage frequency:</strong></td>
<td>once every 3 or 4 weeks</td>
</tr>
<tr>
<td><strong>Dose:</strong></td>
<td>variable, as determined during pre-study period (0.3-1.0 g/kg BW/4 weeks)</td>
</tr>
<tr>
<td><strong>Mode of Administration:</strong></td>
<td>IV</td>
</tr>
<tr>
<td><strong>Batch number(s):</strong></td>
<td>LE12L408AE, LE12L408AK, LE12LG60AD, LE12M072AC, LE12M318AD, LE12MG15AE, LE12N018AC.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Immune Globulin Subcutaneous (Human) (IGSC), 20%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage form:</strong></td>
</tr>
<tr>
<td><strong>Dosage frequency:</strong></td>
</tr>
<tr>
<td><strong>Dose:</strong></td>
</tr>
</tbody>
</table>
  - Epoch 2: 145% of the IGIV, 10% dose  
  - Epoch 3: Adapted dose (was found to be 145% of th IGIV, 10% dose)  
  - Epoch 4: Individually Adjusted dose |
| **Mode of Administration:** | SC |
| **Batch number(s):** | LE13N001AB, LE13N001AD, LE13N001AE, LE13N003AB, LE13N003AE, LE13NA01AB, LE13NA01AE, LE13NA01AF, LE13NA03AB, LE13NA03AC, LE13P002AB, LE13PA02AB. |

<table>
<thead>
<tr>
<th>Placebo/Control/Comparator</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of treatment:</strong></td>
<td>Approximately 20 months for subjects enrolled earlier in the study, and 17 months for subjects enrolled after the Adjusted Dose was already available</td>
</tr>
</tbody>
</table>

**SUBJECT SELECTION**

<table>
<thead>
<tr>
<th>Planned</th>
<th>70 subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyzed</td>
<td>77 subjects in Epoch 1, 45 in Epoch 2, 74 in Epoch 3 and 70 in Epoch 4</td>
</tr>
</tbody>
</table>
DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION

Inclusion Criteria

Subjects who met ALL of the following criteria were eligible for this study:


2. Subject was 2 years or older at the time of screening, and had a minimum body weight of 13 kg.

3. Written informed consent was obtained from either the subject or the subject’s legally authorized representative prior to any study-related procedures and study product administration.

4. Subject had received a stable monthly equivalent dose (i.e. without need for dose adjustment due to lack of efficacy or low trough IgG levels) of IgG at an average minimum dose equivalent to 300 mg/kg BW/4 weeks and a maximum dose equivalent to 1.0 gram/kg BW/4 weeks for a minimum of 12 weeks prior to first treatment with IP in the study. The reason for using doses > 600mg/kg BW / 4 weeks were to be documented on the appropriate CRF. Examples of pre-study dosing frequency:
   a. IV at mean intervals of approximately 3 or 4 weeks or
   b. SC at mean intervals of approximately 1 or 2 weeks
   c. SC alternative treatment schedule (e.g. 2x/week)

5. Subject had a serum trough level of IgG > 500 mg/dL at screening.

6. Subject was willing and able to comply with the requirements of the protocol

Exclusion Criteria

Subjects who met ANY of the following criteria were not eligible for this study:

1. Subject had a known history of or was positive at screening for one or more of the following: hepatitis B surface antigen (HBsAg), polymerase chain reaction (PCR) for hepatitis C virus (HCV), PCR for human immunodeficiency virus (HIV) Type 1/2.

2. Abnormal laboratory values at screening met any one of the following criteria (abnormal tests could be repeated once to determine if they persisted):
   a) Persistent alanine aminotransferase (ALT) and aspartate amino transferase (AST) > 2.5 times the upper limit of normal for the testing laboratory
   b) persistent severe neutropenia (absolute neutrophil count [ANC] ≤ 500 /mm³)


In order to request the publications, please e-mail medinfo@Baxalta.com
3. Subject had creatinine clearance (CLcr) value < 60% of normal range for age and gender, either measured, or calculated according to the Cockcroft-Gault formula\(^{\text{viii}, \text{ix}}\):

\[
CL_{cr} = \frac{(140 – \text{Age [in years]}) \times \text{Body weight (in kg)}}{72 \times \text{Serum Creatinine (in mg/dL)}}
\]

for males:

\[
CL_{cr} = \frac{(140 – \text{Age [in years]}) \times \text{Body weight (in kg) \times 0.85}}{72 \times \text{Serum Creatinine (in mg/dL)}}
\]

for females:

4. Subject had been diagnosed with or had a malignancy (other than adequately treated basal cell or squamous cell carcinoma of the skin or carcinoma in situ of the cervix), unless the disease-free period prior to screening exceeded 5 years.

5. Subject was receiving anti-coagulation therapy or sickle cell disease with crisis within 12 months prior to screening or had a history of thrombophilia.

6. Subject had abnormal protein loss (protein losing enteropathy, nephrotic syndrome).

7. Subject had anemia that would preclude phlebotomy for laboratory studies according to standard practice at the site.

8. Subject had had an acute serious bacterial infection (as defined in Protocol Amendment 3 version 2013 FEB 21, Section 20.6) within the 3 months prior to screening.

9. Subject had an ongoing history of hypersensitivity or persistent reactions (urticaria, breathing difficulty, severe hypotension, or anaphylaxis) following IV immunoglobulin, SC immunoglobulin, and/or Immune Serum Globulin (ISG) infusions.

10. Subject had severe immunoglobulin A (IgA) deficiency (less than 0.07g/L) with known anti-IgA antibodies and a history of hypersensitivity.

11. Subject was on continuous systemic antibacterial antibiotics at doses sufficient to treat or prevent bacterial infections, and, in the opinion of the PI, could not stop those antibiotics for the duration of the study without putting the patient at risk of increased infections.

12. Subject had an active infection and was receiving antibiotic therapy for the treatment of infection at the time of screening.

13. Subject had a bleeding disorder or thrombocytopenia with a platelet count less than 20,000/µL, or who, in the opinion of the investigator, was at significant risk of increased bleeding or bruising as a result of SC therapy.

14. Subject had total protein > 9 g/dL or myeloma or macroglobulinemia (IgM) or paraproteinemia.

15. Subject had severe dermatitis that would preclude adequate sites for safe product administration.

16. Women of childbearing potential meeting any one of the following criteria:
   a. subject presented with a positive pregnancy test
   b. subject was breast feeding
   c. subject intended to begin nursing during the course of the study
   d. subject did not agree to employ adequate birth-control measures throughout the course of the study

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\(^{\text{ix}}\) (140 – Age [in years]) x Body weight (in kg)
17. Subject had participated in another clinical study and had been exposed to an investigational product (IP) or device within 30 days prior to study enrollment (exception: treatment in a previous Baxalta immunoglobulin study).

18. Subject was scheduled to participate in another (non-Baxalta) non-observational (interventional) clinical study involving an IP or device during the course of the study.

**STATISTICAL METHODS**

Acute serious bacterial infection rate and their 99% upper confidence limit were calculated using a Poisson model. Medians, and quartiles and their non-parametric 95% confidence intervals were used for IgG trough levels and other PK parameters. Rates of infection, of fever episodes, hospitalizations, and acute physician visits were calculated using a Poisson model and are presented as point estimate and 95% confidence interval. Descriptive statistics were used for analyses of safety. For dose adjustment, the number and proportion of subjects with dose increases and decreases were given for any reason and broken down by type of reason (IgG trough level <=5g/L, frequency of infections, other medical reason). Analysis of patient-specific outcomes were performed using a Wilcoxon signed ranks test to test hypothesis of change in quality of life (QoL) perception and the statistical significance of change in QoL perception was tested using Bonferroni adjustment.

**SUMMARY – CONCLUSIONS**

**Efficacy Results:**
Analysis of the efficacy results in this study indicates that IGSC, 20% replacement therapy is efficacious in adult and pediatric subjects for the treatment of PIDD with antibody deficiencies:

**Primary Efficacy Outcome:**
A single validated ASBI occurred in 1/74 subjects during IGSC, 20% treatment. The annual rate of validated ASBIs for IGSC, 20% (point estimate 0.012, upper limit of 99% CI: 0.024) was statistically significantly lower than the threshold specified as providing substantial evidence of efficacy.

**Secondary Efficacy Outcome(s):**
- The point estimate of the annualized rate per subject was 2.41 for all infections and less than 1 for sinus infections during IGSC, 20% treatment.
- The AUC during weekly IGSC, 20% treatment at an individualized dose was 108.55% (90%CI: 103.94% - 113.36%, N = 49) of the AUC of IGIV, 10% administered at 3- or 4-week intervals (standardized to 1 week).
- During weekly IGSC, 20% treatment, the median AUC per dose/body mass for total IgG and for antibodies to a clinically relevant pathogen (Haemophilus influenza type b) were similar to the values calculated for IGIV, 10% administered every 3 weeks and only slightly lower than the AUC per dose/body mass obtained for subjects treated with IGIV, 10% every 4 weeks.
- Total IgG trough levels (median) were 15.10 g/L after administration of IGSC, 20% once a week at the individualized dose versus 12.00 g/L or 10.20 g/L after administration of IGIV, 10% every 3 weeks or every 4 weeks, respectively.
- After at least 17 weeks of IGSC, 20% treatment at the individualized dose, the median total IgG trough level was 15.23 g/L (95%CI: 13.59 to 15.70, N= 64)
• The median dose ratio between Epoch 4 and Epoch 1 did not differ substantially from the estimated
dose-adjustment factor based on PK data in Epoch 1 and Epoch 2.
• During IGSC, 20% treatment, the point estimate for the annualized rate of days off school/work was
less than 2 days. The annualized rate of days on antibiotics was approximately 58 days. The
annualized rate of hospitalizations and of days hospitalized were less than 1 day each. The annualized
rate of acute physician visits or visits to the emergency room due to infection or other illness was less
than 1.
• No IP dose adjustment due to an increase in the incidence of infections or IgG trough levels being
lower than the protocol defined minimum of 5 g/L IgG, was required during the study.
• Treatment convenience score (TSQM-9 questionnaire) and treatment interference score (LQI
questionnaire) significantly improved across all age groups during IGSC, 20% treatment compared to
IGIV, 10% treatment.

Safety Results:
• No SAEs occurred that were considered by the investigator to be related to IGSC, 20% treatment.
• One SAE of headache assessed by the investigator as related to IGIV, 10% administration, did not
constitute a new unexpected adverse reaction.
• No subject died during the study.
• No severe non-serious AEs were reported that were considered related to IGSC, 20% treatment.
• Most related AEs were mild or moderate and transient in nature.
• For 99.8% of infusions to administer IGSC, 20%, there was no tolerability concern: no infusion rate
reduction was required; no infusion had to be interrupted or stopped.
• According to MeDRA preferred term classification, the most common AEs related to IGSC, 20% treatment were “headache”, “infusion site pain”, “infusion site erythema”, “nausea”, “fatigue”,
dizziness”, “myalgia” and “infusion site pruritus”, “migraine” and “burning sensation”.
• The rate per subject of non-serious related AEs (including or excluding infections) was 2.122 under
IGSC, 20% and 1.039 under IGIV, 10% treatment.
• The rate per infusion of non-serious related AEs (including or excluding infections) was 0.036 under
IGSC, 20% and 0.247 under IGIV, 10% treatment.
• One or more related local non-serious AEs were experienced by 24.3% of subjects under IGSC, 20%, and
2.6% of subjects under IGIV, 10% treatment.
• The proportion of infusions associated with one or more local AE was 1.8% under IGSC, 20%, and 0.9% of infusions under IGIV, 10% treatment.
• The rate of related systemic non-serious AEs per infusion was 0.021 during IGSC, 20% treatment and
0.241 under IGIV, 10% treatment.
• The rate of causally-related and/or temporally associated non-serious AEs (excluding infections) per
infusion was 0.064 in subjects receiving IGSC, 20% infusions and 0.309 during IGIV, 10% administration.
• For IGSC, 20% administration, a median maximum volume of 39.50 mL/site was infused at a median
maximum rate of 60 mL/hr/site, for a median number of 2.0 sites/infusion.
• An infusion rate per site of 60 mL/hr was achieved by 87.8% of subjects aged 16 to<65 years and
88.9% of subjects aged 65 years and older.
Conclusion:
IGSC, 20% administered SC at an individually adjusted dose was safe in adult and pediatric subjects with PIDD. The low annual rate of validated ASBI meeting the predefined criteria, the low incidence of any infections, and the maintenance of protective trough levels for total IgG and specific antibodies demonstrate the efficacy of IGSC, 20% treatment. An excellent tolerability profile across all age-groups enabled infusions to be administered at higher rates and volumes, leading to shorter infusion times and fewer needle-sticks. As observed in this study, a well-tolerated treatment can have a substantial impact on the perception of the illness and the overall quality of life for subjects on life-long therapies.

Date of Report: 2015 JUN 26