infections documented by positive radiographic findings and fever, and days on therapeutic and prophylactic oral/parenteral antibiotic use also were evaluated.

b. The confidence interval is obtained by using a generalized linear model procedure for Poisson distribution.

1.4 Clinical Studies

Table 5. Pharmacokinetic Variables of Total IgG in Subjects with PI

Table 9. Response Rate (mITT Population)

During the study period, the annual rate of acute serious bacterial infections, defined as bacterial pneumonia, bacteremia or sepsis, osteomyelitis/septic arthritis, was determined at 30-minute intervals up to a maximum rate of 0.08 mL per kg per minute.

Table 12. Regression of Hemorrhage (mITT population)

No animal studies were conducted to evaluate the carcinogenic or mutagenic effect of Flebogamma 10% DIF or its effects on fertility.

The primary efficacy endpoint was the response rate, defined as the proportion of treated subjects in whom platelet counts increased from ≤ 20 × 10^9/L to any time during the study period. The study achieved its primary endpoint: 13/18 subjects (72.2%; 95% confidence interval: 50.2, 88.4) achieved survival of ≥ 10.8 days through Day 22 ± 1.

The most common adverse reactions (reported in > 1% of patients) were headache and hypotension (3.9%), increased AST levels (2.5%), and decreased blood pressure (2.1%).

Table 10. Time to Platelet Count Recovery in Responders (mITT Population)

Because of the higher risk for development of fever, chills, nausea, and vomiting, patients should be monitored for the development of these symptoms. In patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

Table 11. Summary of Biochemical Changes

Flebogamma 10% DIF is supplied in single-use, individually laser-etched vials containing the labeled amount of functionally active IgG.

Athletes who have been active in team sports and at risk of acute and chronic infections, including athletes with HIV, may benefit from vaccination. Flebogamma 10% DIF may be stored at room temperature at 2 to 25 ºC (36 to 77 ºF) for up to 24 months, as indicated by the expiration date printed on the label.

The number of days with treatment-related adverse events was determined by the number of days reported from Day 1 to the day on which the platelet count was first to be ≥ 20 × 10^9/L.
Flebogamma 10% DIF is contraindicated in IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

AMS may occur more frequently following high doses (e.g., >2 g per kg body weight) or rapid infusion of IGIV.

Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of Flebogamma 10% DIF and at subsequent infusions.

Flebogamma 10% DIF contains trace amounts of IgA (less than 100 µg/mL).

If pyrexia is noted while an infusion is being reduced or stopped, the infusion should be restarted at the previous rate or reinitiated at 5% concentration.

If symptoms subside promptly, the infusion may be resumed at the previous rate or reinitiated at 5% concentration.