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Asian Bridging Case Study 1

A Randomized, Open-Label Study to Characterize the Pharmacokinetics , Pharmacodynamics, and Safety of Multiple Doses of XXX X in Healthy Japanese and Non-Japanese Subjects

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Key Elements:
- Inpatient
- Specialty Population – Matching Required

Phase: 1
Indication: Japanese Bridging Study
# of Subjects : 50 Japanese and 50 Caucasian
Study Duration: 28 day screening period followed by 5 treatment periods and a follow up period. Each period consisted of 2 nights/3 days inpatient and 3 of the 5 periods included outpatient visits.

Primary Objective
Characterize the pharmacokinetic profile of XXXX following administration of 0.3, 1, 2, or 3 mg/kg to healthy Japanese and non-Japanese subjects by assessing serum drug concentrations over time.

Secondary Objective
Characterize the safety profile of XXXX following multiple dose administration of 0.3, 1, 2, or 3 mg/kg to healthy Japanese and non-Japanese subjects through a variety of assessments as well as assess the immunogenicity of XXXX.

Pharmacokinetics
Blood samples for analyses were collected as follows:
- Periods 1 and 5: prior to infusion, upon completion of infusion, and 12 and 24 hours after start of infusion on day 1, as well as on days 3, 5, 7, 10, 14 (±1 day), and 21 (±1 day)
- Periods 2 and 4: prior to infusion, upon completion of infusion, and 12 and 24 hours after start of infusion on day 1
- Period 3: prior to infusion, upon completion of infusion, and 12 and 24 hours after start of infusion on day 1, as well as on day 3

Pharmacodynamics
Blood samples for measurement of serum IL-5 and blood eosinophils were collected at the same time points as the pharmacokinetic samples.

Immunogenic ity
Blood samples for measurement of anti-drug antibodies were obtained prior to study drug administration in periods 1 and 3 and at the first and last follow-up visits.

Japanese Subjects Criteria
- Born in Japan
- Japanese parents and grandparents
- Lived less than 5 years outside Japan
- Passport issued from Japan
- No plans to leave the US between the baseline visit and completion of follow-up visit 1

Safety
- Adverse event reports throughout the study
- Clinical laboratory test results on the day prior to study drug administration in each period, at the final assessment, and at the last follow-up visit
- Immunoglobulin measurements on the day prior to study drug administration in period 3 and at the final assessment
- Vital signs measurements throughout the study
- ECG findings at each pharmacoinetic time point and at the final assessment
- Physical examination findings at the final assessment
- Brief neurologic exam findings following study drug administration in period 3 and at the first and last follow-up visits
- Concomitant medication usage throughout the study