**RESULTS**

**NHP Population PK Model**

- As shown in Figure 1, the NHP population PK model was described by a linear three-compartment model. The alpha, beta, and gamma half-lives were 0.5, 2.7, and 138 hours, respectively.
- The weight effect was a covariate for volume of the central compartment (proportional), clearance (proportional), and error (proportional) using a typical weight of 3 kg.

**Humanization**

- The NHP-determined SOL dosing regimen for humans, 800 mg PO on Day 1 followed by 400 mg PO Q24h, 400 mg PO on Day 1 followed by 300 mg PO Q24h, and 1200 mg PO on Day 1 followed by 600 mg PO Q24h, are shown in Table 2. The first infusion of each is a 4 hour infusion, during which the absorption phase occurs in humans.
- The remaining doses for each day are 1 hour infusions.

**METHODS**

- **Population PK Model Development**
  - Development of NHP population PK model to construct NHP IV dosing regimens to allow the NHP efficacy study to closely match those predicted for humans.
  - Developed NHP population PK model using the final NHP PK model described above.
  - Developed the NHP population PK model based on a tiered hierarchical model.

**Humanization**

- The NHP-determined SOL dosing regimen for humans, 800 mg PO on Day 1 followed by 400 mg PO Q24h, 400 mg PO on Day 1 followed by 300 mg PO Q24h, and 1200 mg PO on Day 1 followed by 600 mg PO Q24h, are shown in Table 2. The first infusion of each is a 4 hour infusion, during which the absorption phase occurs in humans.
- The remaining doses for each day are 1 hour infusions.

**RESULTS**

**Humoralization of Solithromycin Non-Human Primate Pharmacokinetic Profiles to Improve Pharmacokinetic-Pharmacodynamic Translation**

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**HUMORALIZATION**

- **Humoralization** refers to the process of increasing the half-life of a drug by using albumin, human immunoglobulins, or other macromolecules to improve pharmacokinetic and pharmacodynamic properties.

**REFERENCES**


**ACKNOWLEDGEMENTS**

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**DISCUSSION/CONCLUSIONS**

- The NHP-determined SOL dosing regimen was developed for NHP to match target human PK profiles.
- The NHP-determined SOL dosing regimen was demonstrated to be a reasonable match for target human SOL profiles.
- The NHP-determined SOL dosing regimen was particularly well matched for target human SOL half-life and maximum concentration.
- The NHP-determined SOL dosing regimen was a considerable improvement over the current target.

**REFERENCES**


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