FIRST-IN-MOUSE™ PK

Our First-in-Mouse™ PK studies are designed on our client's need to understand the IP/PO or IP/SC PK profile of two molecules within their new chemical series and preliminary protein binding. Upon completion of the First-in-Mouse™ studies, Xyzagen can discuss possible PK screens, such as cassette dosing or cassette analysis, to 3 time point PK screens, as well as our First-in-Rat™ PK.

COST: $15,000 / COST FOR PRESENTATION OF DATA BY SEX: $17,000

STUDY DESIGN

(PER COMPOUND; TWO COMPOUNDS)

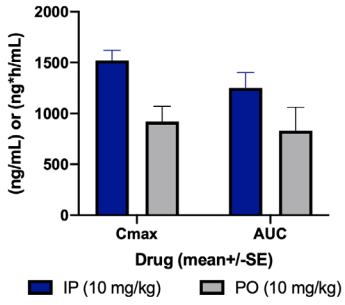
- 12 male & 12 female mice (total of 48 mice for two compounds)
- 21-24 g per mouse; CD-1 strain (can alter strain depending on client efficacy pharmacology models)
- IP and PO (or SC) Route
  - 10 mL/kg volume, 10 mg/kg, 1 mg/mL
  - Drug requirements: minimum of 12 mg, 16 mg preferred
  - 0.5% Methyl Cellulose vehicle
  - 1 M/F mouse/time point/route: Time points 5, 15, 30 min, 1, 2, 4 h
- Tier 1 bioanalytical method development with one compound acting as the ISTD for the other compound
- Protein binding assessed at 3uM conc with N=3 replicate at 2 h on Thermo Fisher™ RED device (no positive control)

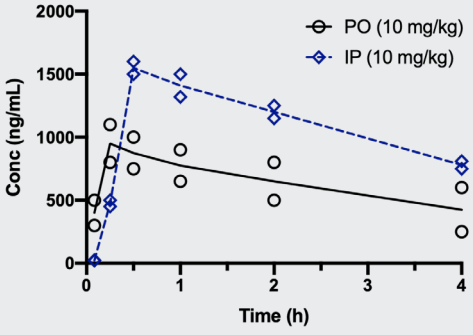
RESULTS

- Sparse sampling PK Analysis (for each route/sex combined): AUClast, AUCinf, Cmax, MRTlast, MRTinf, %Extrap, Tmax, Tlag, T1/2; Relative bioavailability of PO(SC) to IP based on AUClast or AUCinf. Summary tables of PK parameters and PK concentrations, body weights, clinical signs, linear and semilog Mean (SD) concentration time plots, scatter plots.
  - If >2-fold exposure difference between sex then PK concentration presented by sex and group.
  - Protein binding presented as free fraction

REPORT

- PDF bookmarked report for use in IND submission or Due Diligence
- Excel file of concentration time data
- Plasma stored for 1 year for potential future metabolite ID





EXPERIENCED SCIENTISTS IN PHARMACOKINETIC STUDY DESIGN, IMPLEMENTATION, ANALYSIS, AND REPORTING.

Xyzagen has over 25 years of early drug discovery experience. Our lead scientists have advanced many programs from early pharmacology through Phase 2 clinical development and approval. The challenge to identify a chemical series that has pharmacological activity and is drug-able is greater with limited resources. Pharmacokinetics are critical in defining the drugability of a new chemical series. Talk to us.

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