ALTASCIENCES
CLINICAL SERVICES

Impaired Renal and Hepatic Function

Altasciences' Patient Access

- 3 months to complete enrollment of 8 patients per group of severe, moderate and mild renal impairment patients, and the healthy matches
- Access to referring physicians and industry experts to maintain and increase patient database
- Searchable database to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use, and BMI
- Access to matching healthy control subjects through database of over 120,000 participants; 40,000 of which are active
- Full and two-stage adaptive integrated designs in accordance to FDA and EMA guidances
- Administration of the investigational drug to groups with mild, moderate and severe impairment via multiple routes, including parenteral injections
- Full project management for multi-site trials, including operational support
- Setup for medical, scientific, regulatory and operational procedures
- Support services, including customized protocol design, data management, bioanalysis, biostatistics and reporting

Impaired Renal Function

- Strategic alliance with Hôpital Maisonneuve-Rosemont, an industry leading nephrology site
- **1,300+** patients with mild, moderate and severe renal function impairment
- Access to End Stage Renal Disease (ESRD) patients, whether or not dialysis is required
- Pharmacokinetic assessment of dosage adjustment requirements in patients with impaired renal function
- An Open-label, Non-Randomized, Parallel Group Study of Deferiprone in Subjects with Mild, Moderate, Severe, or No Renal Impairment

Impaired Hepatic Function

- Strategic collaborations with sites in Canada and/or the United States.
- Access to **1,000+** patients with mild, moderate and severe hepatic function impairment
- Studies designed in accordance with current FDA and EMA guidances
- Assessment of the impact of hepatic metabolism and/or excretion on the drug's pharmacokinetics profile to make informed dosing recommendations

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Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- High throughput bioassays for drug quantitation (operating 24/7), capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Biostatistics

- All Programming done using SAS®
- Randomization list
- Statistical Analysis Plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data e.g. safety lab
- Creation of CDISC-compliant FDA submission-ready package

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