Impaired Renal Function

Algorithme Pharma’s Patient Access

- **1300+** patients with mild, moderate and severe renal function impairment, and patients requiring dialysis
- Strategic alliance with Hôtel Maisonneuve-Rosemont hospital, an industry leading nephrology site
- Easy access to matching healthy control subjects through database of over 120,000 participants, 40,000 active
- Ongoing outreach efforts to maintain and increase patient database
- Searchable database to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use, and BMI

Experience

- Six months to complete a study for 32 patients from protocol to Clinical Study Report, including all four stages (mild, moderate and severe) and healthy control subjects
- Assessment of dosage adjustment requirements for marketed drug products in patients with impaired renal function
- Administration of the investigational drug at the same dosage, to groups with mild, moderate and severe renal impairment
- Study design in accordance to FDA and EMA guidances

Clinical Expertise

- Reduced and full PK studies conduct
- Full project management for multi-site trial, including operational support
- Setup for medical, scientific, regulatory and operational procedures
- Support services, including customized protocol design, data management, bioanalysis, biostats and reporting
- Administration of medication via multiple routes, including parenteral injections

» An Open-label, Non-randomized, Parallel Group Study in Subjects With Mild, Moderate, Severe, or No Renal Impairment
Support Services

Bioanalysis
- Our 20,000-sq.-ft. GLP-Compliant Bioanalytical Facility for Preclinical to Clinical Support
- 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

Pharmacokinetic (PK) Analysis
- Comprehensive Clinical PK and PD Data Analysis and Interpretation
- Robust non-compartmental analysis using WinNonlin® v6 (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 updated regulations
- Clinical trial protocol development
- Protocol review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Data Management
- Team with over 20 years of experience
- Medrio’s eClinical EDC
- 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
- Scientific Project Manager (Project Leader) oversees the complete program conduct and deliverables from study protocol to reporting
- Extensive expertise in managing clinical trials across a wide range of therapeutic areas
- Close collaboration with key departments and external contractors to ensure seamless and timely communications for successful project completions

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