Supporting GLP-1 Receptor Agonist & Weight Reduction Drug Development

Glucagon-like peptide 1 (GLP-1) receptor agonists (RAs) are popular therapies approved for the treatment of type 2 diabetes and weight reduction, along with diet and exercise. Stemming from their success, novel GLP-1 products along with other incretin (gut hormone) drugs, are now in development. It is anticipated that these next generation of weight reduction treatments will offer better safety profiles, more convenient drug administration (e.g. oral products or less frequent subcutaneous dosing) and improved patient adherence.

Leverage Celerion's decades of experience and expertise in supporting GLP-1 drug development. From comprehensive clinical pharmacology support to innovative bioanalytical efficiencies, we provide reliable and timely results tailored to meet your study needs. Celerion also has experience in designing and conducting trials to evaluate GLP-1 RA combination products, including therapies to mitigate gastrointestinal adverse effects or muscle mass loss.

Evaluation of Adiposity & Insulin Sensitivity

Celerion offers a full range of adiposity (fat mass) and insulin sensitivity assessments for early signals of drug efficacy. These capabilities include:

- Body weight, waist circumference, DEXA, MRI and bioimpedance
- Food intake and hunger/satiety VAS, food diaries
- Oral glucose (OGTT) and mixed meal (MMTT) tolerance tests
- Continuous glucose monitoring (CGM)
- Adipokine and glucose handling biomarkers
- Adipose and skeletal muscle tissue biopsy

Celerion Differentiators:

Experience:

- More than 20 studies completed with therapies targeting the incretin pathway, GLP-1RA and dipeptidyl peptidase-4 (DPP-4) inhibitors
- Our GLP-1 experience includes Phase I-IIa studies to evaluate safety, efficacy, pharmacokinetic properties as well as potential drug interactions
- Experience with insulin sensitizing drugs & microbiota products for weight loss

Expertise:

- Subject matter experts with 20+ years of obesity and diabetes research experience

Efficiencies:

- Vast database of obese and overweight participants
- On-site registered dieticians to support specialized diets and meal planning
- Array of exploratory biomarkers: GLP-1, leptin, adiponectin, ghrelin, TNFα, hsCRP and more

Safety Assessments for Weight Reduction Drugs in Development

Common adverse effects associated with current weight reduction therapies should be thoroughly monitored and investigated. Key safety evaluations include:

Gastrointestinal Adverse Events (AEs): Severity of nausea, vomiting and diarrhea events can be explored by questionnaires and Bristol stool chart assessments, respectively

Cardiovascular Liability: Proarrhythmic risk (i.e. QTc prolongation) evaluated via Holter ECG monitoring

Drug Specific Safety Assessments: Depending on the drug modality and potential off-target effects, consider immunogenicity testing, changes in muscle mass (via DEXA), and C-SSRS questionnaires for centrally acting drugs

Injection Site Reactions: Applicable for subcutaneous and intravenous drug administration

Potential Adverse Reactions: Safety labs to monitor potential rare, but serious AEs such as serum amylase and lipase for pancreatitis or serum calcitonin for medullary thyroid cancer

Bioanalytical Considerations

We also offer full bioanalytical capabilities to support peptide drug development with state-of-the-art platforms for peptide analysis at our Lincoln, NE and Zurich, CH bioanalytical laboratories:

- LC-MS/MS
- ELISA
- SIMOA
- MSD
- AlphaLISA
- Gyrolab

Clinical Pharmacology Studies to Support GLP-1 RA Studies

Celerion has the experience and expertise to support a range of clinical pharmacology studies tailored to GLP-1 RA drug development:

- First-in-human (SAD & MAD) studies
- Proof-of-concept (Phase Ib and IIa) studies
- Acetaminophen absorption effect study to evaluate delayed gastric emptying
- Drug-drug interaction (DDI) studies with concomitant medications such as metformin, oral contraceptives, statins, etc.
- Renal impairment PK studies
- Cardiodynamic assessment (TQT or cQT)

RESOURCES:

Leaders in Early Metabolic Disease Studies

Drug Absorption & Impact of Food, Gastric pH, Gastric Emptying and GLP-1 Agonists Webinar

GLP-1 Agonist-Induced Delayed Gastric Emptying – A Clinical Pharmacology Perspective