Why Celerion for Early NASH Drug Development

PROVEN EXPERIENCE:

– Celerion has conducted over 100 clinical studies for investigational products targeting metabolic diseases such as diabetes, obesity and nonalcoholic steatohepatitis (NASH).
– Our comprehensive NASH experience covers all aspects of early drug development; from first-in-human to proof-of-mechanism studies to biomarker development.
– Our capabilities also extend to proof-of-concept and NDA-labeling studies such as hepatic impairment pharmacokinetic (PK) studies.

INNOVATIVE ASSESSMENTS:

Gain early signals of efficacy with state-of-the-art noninvasive imaging assessments, sophisticated procedures and biomarkers

– FibroScan® available at Phoenix and Lincoln clinics
– Imaging centers with MRI-PDFF and MRE located near US clinics
– De novo lipogenesis stable label isotope studies
– On-site liver biopsy capabilities
– Catalog of analytically validated NASH biomarkers including CK-18, C4 (bile acid derivative), IL-6, IL-1β, and more

ACCESS TO SUBJECTS:

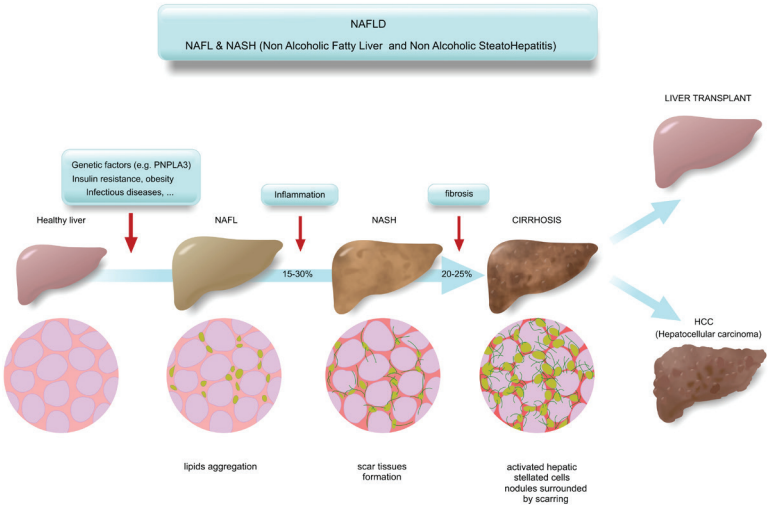
Celerion has a robust database of healthy participants for early phase studies, and partners with a network of patient sites for access to biopsy-proven NASH patients, resulting in a seamless transition from first in-human to proof-of-concept studies

– Vast database of healthy participants for early phase studies
– Database of >7000 obese but otherwise healthy participants
– More than 500 participants pre-screened with FibroScan®
– Network of clinical sites with biopsy-proven NASH patients
– Partner specialized hepatic impairment clinics for pharmacokinetic (PK) studies

NETWORK OF HEPATIC IMPAIRMENT CLINICS:

Since NASH drugs are intended for a hepatic impaired population, it is imperative to perform PK analysis early in development to determine if dose adjustments are required.

- Celerion collaborates with expert centers specializing in hepatic and renal impaired PK studies.
- Our partner sites have a database of mild, moderate, and severe patients.
- Celerion provides full service management, streamlining the entire study to save time and costs.



RELATED RESOURCES

Assay Validation and Clinical Performance of Chronic Inflammatory and Chemokine Biomarkers of NASH Fibrosis

Challenges and Solutions with Bioanalysis of Soluble Biomarkers: A Case Study for Non-Invasive NASH Biomarkers

The FibroScan® Advantage in Early NASH Clinical Studies

CASE STUDY – HEALTHY PARTICIPANT LIVER BIOPSY

NEED

- The client wanted to evaluate liver-plasma drug exposure ratio after multiple doses of a small molecule administered in healthy participants.

APPROACH

- Coordinated a team of Specialists to come onsite to our mini-phase ward for the liver biopsy procedure including a board-certified Hepatologist, an Anesthesiologist to provide conscious sedation, and Ultrasound Technician to mark the biopsy site.
- Two liver biopsy passes provided sample tissue for drug concentration, histological assessments and biomarkers of interest.
- Blood samples were taken within minutes of the liver biopsy procedure for time-matched PK assessments.

BENEFIT

- The mini-phase ward offered an ideal setting to safely carryout the biopsy procedure for an entire study cohort, while maintaining participant privacy.
- A dedicated team of medical support staff and liver tissue processors minimized sample variability.
- Per protocol, participants were to be discharged the following day. However, with over 350-bed capacity, we offered participants a Concierge Stay, giving them extra time to recoup from the procedure.