



NASH Fibrosis Model



COMPARATIVE BIOSCIENCES, INC.
A TRANSLATIONAL APPROACH TO PRECLINICAL RESEARCH

COMPARATIVE BIOSCIENCES, INC.

Premier Preclinical Contract Research Organization

- **20 years** of experience
- Conveniently **located in the heart of Silicon Valley**, amidst many biotech companies
- **State of the art, purpose-built facility**
- Approximately **30 employees**
- **Highly experienced staff**
- **GLP, OECD, FDA, USDA, OLAW**
- **AAALAC Accreditation**



Scientific Overview

We specialize in developing a custom study plan in order to best meet your pre-clinical research needs and prepare for regulatory submission.

- GLP and Non-GLP
- Toxicology
- Efficacy
- Pharmacokinetics
- Pharmacology
- In-house histopathology, immunohistochemistry & TCR



CBI Animal Facility

- **Dedicated Rooms:**
 - Six small animal and four large animal rooms
 - Two procedure rooms, two surgery rooms
 - Two rooms with ventilation for immuno-compromised animals
- **Air Quality Systems:**
 - HVAC, light control in each room
 - 10-15 air changes per hour with positive air flow and filtered air
- **Cleanliness:**
 - Dual corridor system with pass-thru Basil cage washer
 - Daily environmental monitoring
 - Regular disease, bacterial and water surveillance
- **24/7 Staff**



Test Articles

- **Small molecules**
- **Biologics**
 - Peptides
 - Antibodies
 - Vaccines
 - siRNA & Nucleic Acids
- **Stem cells & cell therapies**
- **Devices**
- **Device and drug combinations**
- **Regenerative Medicine**



Toxicology Studies

- **GLP and Non-GLP studies**
- **Single-dose and multiple-dose studies**
- **All routes of administration**
- **Acute & chronic studies**
- **Discovery and Investigative toxicology**
- **Non-standard routes of administration**
- **Complete, prompt reports**



Pharmacokinetic Studies

- **GLP and Non-GLP studies**
- **Single-dose or multiple-dose studies**
- **Sample analysis from blood, urine, CSF, feces**
- **Measure C_{max}, T_{max}, AUC**
- **Metabolic and pharmacodynamics studies**
- **Non-standard routes of administration**



Pharmacology and Efficacy Studies

- **Pharmacology and efficacy modeling in multiple areas**
- **Custom model development**
- **Surgical modeling**
- **Investigative studies**
- **Combination GLP efficacy and toxicology**



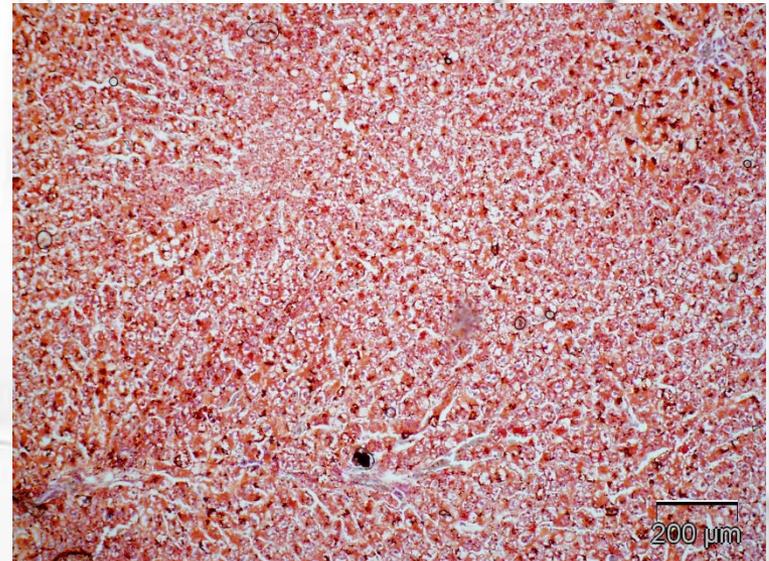
Pharmacology and Efficacy Studies

- **Animal Disease Models for Multiple Indications**
 - Ocular
 - Otic
 - Cardiovascular
 - Inflammation
 - Dermatology
 - Arthritis
 - Allergic and Immune Mediated studies
 - Wound healing and scarring
 - Renal and Hepatic Models
 - Anti-infective studies
 - Oncology and xenograft
 - Botulinum toxin
 - Central nervous system
 - Regenerative medicine
 - Surgical Models



Procedure

- We work with ZDF rats weighing approximately 500 grams that are singly housed
- Blood glucose level is monitored by tail nick and hand-held monitor
 - Once from all animals before start of dosing to establish base line
 - Three times per week from animals from day 0 to study end.
 - On the day of necropsy.
- Body weight is measured three times per week
- Special clinical observations: animals are scored three times per week for general health including a score for the following parameters.
 - Dehydration
 - Appearance
 - Breathing



Oil red H&E



Service and Quality

- ***Thoroughness in planning and execution is key to a successful study.*** All protocols are vetted and approved by multiple personnel. Our QAU has a rigorous training program. All non-GLP studies are conducted in the spirit of GLP.
- ***We believe in sound science.*** Our ratio of scientists to non-scientists is one of the highest in the industry. Every study director is a PhD-level scientist.
- ***We believe in communication.*** Timely responses to your inquiries and frequent updates on your study are mandatory.
- ***We welcome visitors.*** You are always welcome at CBI to meet the staff, tour the laboratory and discuss the progress and results of your study.



Our Staff

- **Study Directors**

- PhD level scientists
- Appointed by management for each job
- Serves as single point of control and is responsible and accountable for study conduct and scientific interpretation
- Experienced attentive and communicative
- Rapid study initiation and report preparation

- **Research Associates**

- Bachelor Level Scientists
- Extensive technical training

- **Quality Assurance**

- Rigorous Training Program



Summary

- **CBI provides state of the art:**
 - Toxicology
 - Pharmacokinetics
 - Efficacy
 - Pharmacology
 - In house histopathology
- **Experienced attentive and communicative study directors**
- **Rapid study initiation and report preparation**
- **Established, stable business**
- **Regulatory compliance**
- **Favorable pricing structure**

