



# CBI

## Dermal Studies at CBI

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COMPARATIVE BIOSCIENCES, INC.  
A TRANSLATIONAL APPROACH TO PRECLINICAL RESEARCH

# COMPARATIVE BIOSCIENCES, INC.

## Premier Preclinical Contract Research Organization

- **Over 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**



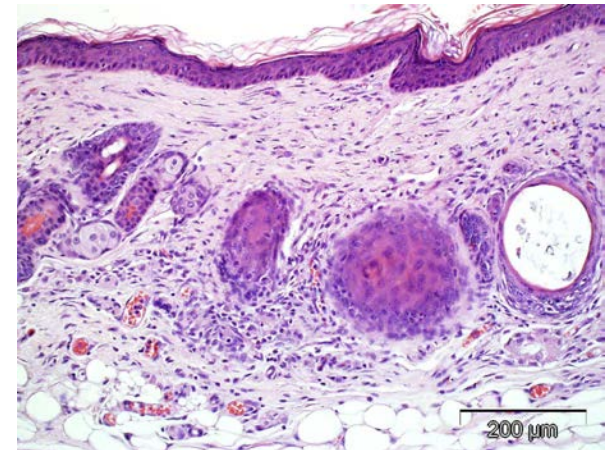
# Dermal Test Articles

- **Topical-intact and abraded skin; wounds, burns**
- **Covered vs Exposed Applications**
- **Intradermal**
- **Subcutaneous**
- **Systemic**
- **Numerous Classes of Compounds**
  - **Small molecules**
  - **Biologics**
  - **Stem cells & cell therapies**
  - **Devices**
  - **Device and drug combinations**
  - **Regenerative medicine-stem cells**



# Dermal Toxicology Studies

- **Topical, systemic, normal and abraded**
- **Intact skin, wounds, burns, other pharmacology components**
- **GLP and Non-GLP studies**
- **Single & multiple dose studies**
- **All routes of administration**
- **Acute & chronic studies**
- **Discovery and Investigative toxicology**
- **Local Irritation, Buehler sensitization**
- **Complete, prompt reports**



# Pharmacokinetic Studies

- **GLP and Non-GLP studies**
- **Assessment of blood, tissue biopsies**
- **Single or multiple dose studies**
- **Sample analysis from blood, urine, feces, tissue biopsies**
- **Bioanalytical method development**
- **Measure C<sub>max</sub>, T<sub>max</sub>, AUC**
- **WinNonlin PK/PD Modeling**
- **Metabolic and pharmacodynamic studies**
- **Non-standard routes of administration**



# **Dermatology Pharmacology and Efficacy Studies**

- **Dermatology pharmacology and efficacy modeling**
- **Custom model development**
- **Surgical modeling**
- **Investigative studies**
- **Combination GLP efficacy and toxicology**



# Pharmacology and Efficacy Studies

- Scar formation-hypertrophic scar
- Thermal burns
- UV light burns
- Wound healing and scarring
- Local and topical irritation
- Allergic and immune mediated studies-DTH
- Bleomycin fibrotic: skin and lung
- Anti-infective dermal studies
- Dermal xenografts
- Local sensitization and Buehler
- Regenerative, stem cell medicine
- Custom model development



SKH1 Hairless Mouse





# Typical Study Parameters

**CBI's experience gives you a number of options...**

- Daily clinical observations
- Daily to weekly body weights
- Food consumption
- Clinical pathology
- Draize scoring
- Photography and scoring
- Toxicokinetics or pharmacokinetic
- Surgical biopsies throughout study
- Necropsy
- Histopathology on biopsies and necropsy:
  - Tissue stained with HE, trichrome, other stains upon request
  - IHC for various markers upon request
  - Digital image analysis for wound size, cellular infiltrates, inflammatory markers or other markers
  - Photomicroscopy





# Minipig Topical Dermal Studies

- Minipigs dermal structure recognize as most clinically similar
- Topical dosing can be tailor to fit clinical study design with 10%BSA typically treated



- Ease of handling with Minipig, ~15-20kg



# Service and Quality

- The people at CBI—from the executive team to the study directors to the research associates expect to have to earn your trust and business.
- Our ratio of scientists to non-scientists is one of the highest in the industry. We believe in sound science and every study director is a PhD-level scientist
- 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 communication: timely responses to your inquiries and frequent updates on your study are mandatory.
- 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**

- Full time, dedicated
- Rigorous training program

- **CBI Management**

- Experienced senior scientific management-with large and small pharma experience



# Summary

- **With a focus on skin, 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**

