Preclinical Capabilities

Early stages in ocular drug development

Ora’s preclinical ophthalmic research team has extensive experience, ranging from ophthalmic disease and custom model development to managing and executing animal efficacy, tolerability, and PK studies.

Experience across all facets of preclinical research
• PK, Ocular Irritation (non-GLP safety studies)
• Animal efficacy models (mice, rats, rabbits) spanning a wide range of ophthalmic diseases, including customized study design, depending on compound, indication, and MOA
• State-of-the-art clinical instrumentation and surgical capabilities
• Compound identification and ophthalmic formulation partnerships

Summary of Preclinical Services

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<td>• Topical eye drop</td>
<td>• Fundus imaging</td>
<td>• Tolerability/Irritation/Safety</td>
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<td>• Intravitreal injection</td>
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|  | • Subretinal injection | • Systemic delivery including oral, subcutaneous, intraperitoneal, and intravenous |
|  | • Electroretinograms | • Safety, biocompatibility, and toxicity evaluations |
|  | • Ocular implant delivery/efficacy | • Rabbit, rat, mouse |

COLLABORATIVE APPROACH

Applying synergy with Ora’s clinical, regulatory, and CMC departments to customize your development programs

Developing and managing GLP toxicology programs to support regulatory filings
About our Vivarium
- Approx. 17,000 sq. ft.
- Located in Andover, MA
- Focus on ethics and safety
- OLAW and USDA certified

Ocular Disease Models
Animal disease models are modified to provide a customized and accurate screening in the most efficient and cost-effective manner. Ora also assists with development and management of GLP toxicology programs to support regulatory filings.

Preclinical Ophthalmic Device Development
- Customized study designs depending on device and indication
- Flexible study plans based on client needs - study extensions or early completion
- Ophthalmic-focused staff with specific disease experience across the entire ocular space
- Full clinical capabilities to facilitate smooth transition to first-in-human clinical trials

ALLERGIC CONJUNCTIVITIS
- Short Ragweed Sensitization (mouse)

DRY EYE
- Chronic Dessication Stress (Scopolamine/Low Humidity Chamber) (mouse)
- Acute Inflammatory Stress (ConA/Low Humidity Chamber) (mouse)

CORNEAL HEALING
- Mechanical wound (rabbit)
- Alkali burn (rabbit)
- Chemical burn (rabbit)

OCULAR INFLAMMATION
- Experimental Autoimmune Uveitis (rat)
- Endotoxin Induced Uveitis (rat)
- Post-operative Inflammation (rabbit)

GLAUCOMA - INTRAOCULAR PRESSURE
- Normotensive (rabbit, rat)

GLAUCOMA - RETINAL DEGENERATION
- Optic Nerve Crush (rat)

WET AMD
- Laser-induced choroidal neovascularization (rat)

DRY AMD
- Sodium-iodate retinopathy (rabbit, rat)

RETINAL VASCULAR DISEASE
- VEGF-induced vascular leakage (rabbit, rat)
- STZ-induced diabetic vascular leakage (rat)

CUSTOM MODEL DEVELOPMENT
- Based on client’s needs