Anti-inflammatory therapies have a wide variety of ophthalmic applications. The anti-inflammatory market has experienced robust growth, with U.S. revenues and prescriptions increasing 39% and 16% from 2007 to 2009, respectively (IMS(2009)).

The majority of broad-acting ophthalmic anti-inflammatory agents are typically developed for the treatment of post-operative inflammation after cataract surgery. Additional indications include dry eye and inflammatory conditions of the eyelid, such as blepharitis and meibomitis, as well as uveitis, one of the leading causes of blindness. Eye care providers treat a wide range of ocular inflammatory diseases, but they are restricted to relatively few anti-inflammatory therapeutic options.

Within the indication of lid margin disease, Ora has developed standardized grading scales for blepharitis and meibomitis based on anatomical classifications. These standardized validated photograph control scales have already been utilized in three IND studies.1,2

3 Torkildsen GI, Cockrum P, Meier E, et al. Evaluation of clinical efficacy and safety of tobramycin/dexamethasone ophthalmic suspension 0.3%/0.05% compared to azithromycin ophthalmic solution 1% in the treatment of moderate to severe acute blepharitis/blepharoconjunctivitis. Curr Med Res Opin. 2010 Dec.
Unparalleled Inflammation Expertise

Ora has conducted numerous Phase II – IV anti-inflammatory clinical trials and our research team has extensive experience in comfort, safety, and pharmacokinetic studies, as well as Phase III multi-center international pivotal studies.

The potential for novel anti-inflammatory mechanisms of action has attracted a number of innovative companies to develop ophthalmic formulations, as they search for the most efficient pathway to transform their novel APIs into viable ophthalmic therapies. These companies look to Ora’s capabilities, which include:

- Pre-clinical Proof-of-Concept
- Clinical/Regulatory Strategy
- Study Design
- Site Selection and Qualification
- Clinical Study and Multi-Center Site Management

Case Study: Post-Operative Inflammation

A sponsor with an investigational recombinant protein collaborated with Ora to design a development program to show efficacy in treating ocular inflammation after cataract extraction. Prior to the initiation of the human study, Ora worked with the client on a preclinical study to show efficacy of the compound in rabbits. In the proof-of-concept (POC) dose ranging study, Ora was able to enroll 150 patients in 3 months. The integration of Ora’s preclinical and clinical services allowed the client to quickly evaluate the safety and efficacy of the drug, and make a go/no-go decision.

Case Study: Blepharitis

Blepharitis is one of the most common eye diseases in the world. However, because there are no approved pharmaceutical therapeutic options with a specific blepharitis indication, there exists a significant market opportunity.

A recent example of Ora’s blepharitis expertise was a study of an investigational combination eye drop developed to treat blepharitis. Ora managed the multi-center pivotal U.S. trial, enrolling a total of 399 patients. The trial relied upon Ora’s proprietary scales to first evaluate the patients’ disease states, and then randomize them into one of the three treatment arms.

Contact Us:
Aron Shapiro, Vice President
inflaminfo@oraclinical.com
(978) 494-4899

Ora is your value-added partner – from molecule to marketplace:

Global R&D

- Strategic Consulting
- Study and Clinical Program Design
- Formulation/CMC Management
- Pharmacology/Toxicology
- Preclinical Models
- Clinical: Phase I – IV
- Regulatory Submissions and FDA Interface
- Biostatistics and Data Management
- Medical Writing and Publication Support
- Marketing, Advertising, and Product Commercialization

Models & Methods

- Conjunctival Allergen Challenge (CAC™)
- Hybrid Conjunctival Allergen Challenge (Enviro-CAC™)
- Late Phase CAC™ Model
- Controlled Adverse Environment (CAE™)
- Allergen BioCube™ (ABC)
- Conjunctival Biopsy
- Clinical Scales

Business Development & Creative Business Models

- Product/Pipeline Analysis to Evaluate Assets for Re-Purposing into Ophthalmic Indications
- New Product Incubator
- Strategic Business Planning
- Due Diligence
- Network of Investors and Pharmaceutical Partners