Some allergic conjunctivitis sufferers experience a more severe late-phase allergic inflammation as a component of their ocular allergies. This subpopulation of chronic allergy sufferers (estimated at 30% of the total AC population) is not adequately treated with standard anti-histamine therapy. These patients require more powerful anti-inflammatory agents to alleviate disease symptoms. Previously, Conjunctival Allergen Challenge (CAC) studies very effectively induced the acute allergic response, which was optimal for evaluating antihistamine therapies. However, a single acute exposure did not induce clinically meaningful allergic inflammation. Ora has now introduced a new CAC model to induce allergic inflammation, addressing this unmet need in allergic conjunctivitis drug development. This model provides added controls for screening anti-inflammatory drugs while avoiding the problems associated with the environmental trials.

- Repeated CAC challenges over multiple days to induce chronic inflammatory response
- Ability to demonstrate anti-inflammatory treatment effect with a small N
- Avoids pitfalls associated with environmental trials (inconsistent allergen exposure, large n’s, poor patient compliance, lack of objective measures, variable results)

Ora has been conducting studies in ocular allergy since its founding over 30 years ago. Ora’s continuous innovation approach, “Research on Research,” has developed the most advanced and reliable clinical research models in the ophthalmic arena, and helped our clients garner 19 NDAs in ocular allergy.

Our proprietary models, the Conjunctival Allergen Challenge (CAC™), the Enviro-CAC™, and the Late Phase CAC™ accelerate clinical research timelines in allergy, while lowering standard deviations and yielding reproducible, accurate results. These models are accepted by regulatory agencies in the U.S., Europe and Japan as a standard test system for evaluating ophthalmic anti-allergic agents in Phase I – IV clinical trials. Now, Ora introduces the newest model to target late phase and chronic allergic conjunctivitis – the Simulated Zero Order Kinetics CACTM.
Final Time Point- Itching and Redness - All Visits

Figure 1, 2. Ora’s Proprietary Zero Order Kinetics CAC. Itching and redness prior to and following treatment with placebo or prednisolone phosphate. (Treatment administered between Visits 4 and 5.)

Figure 1.

Figure 2.

Zero Order Kinetics CAC. Eye one the left received treatment with placebo while eye on the right was treated with drug. Note pronounced differences in conjunctival hyperemia.

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

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