



# PARION SCIENCES

2800 Meridian Parkway, Suite 195  
Durham, North Carolina 27713  
(919) 313-1180 (phone)  
(919) 313-1190 (fax)

Parion Sciences, Inc.  
Paul Boucher, President  
919-475-9600  
pboucher@parion.com

## **Parion Sciences Receives FDA Acceptance of the Investigational New Drug Application for Clinical Testing of P-321 Ophthalmic Solution for the Treatment of Dry Eye Disease**

- *Initiation of Phase 1/2a clinical trial in subjects with dry eye disease expected mid-2014*
- *Preclinical data will be presented at the Association for Research in Vision and Ophthalmology Annual Meeting (ARVO) on May 6, 2014*

**Durham, NC (May 1, 2014)** – Parion Sciences, a company dedicated to the development of novel treatments for ocular and pulmonary diseases, announced today that it has received acceptance from the U.S. Food and Drug Administration (FDA) of its Investigational New Drug (IND) application for P-321 Ophthalmic Solution for the treatment of dry eye disease. Preclinical data that supported this approval will be presented in a poster session at the Association for Research in Vision and Ophthalmology Annual Meeting (ARVO) on May 6, 2014, in Orlando, Fla.

“The FDA’s acceptance of our IND marks an important milestone in our ophthalmology program, as we advance P-321 into a Phase 1/2a clinical trial in subjects with dry eye disease,” said Paul Boucher, President, Parion Sciences. “Our program focuses on a novel mechanism of action to restore one of the core causes of the disease, the reduced tear film volume. The potent and long lasting effect of P-321 to hydrate the ocular surface could provide a needed relief to patients suffering from dry eye. We’re excited to begin clinical studies later this year.”

### **About ENaC and P-321**

The epithelial sodium channel (ENaC) plays a key role in the regulation of tear film fluid and is therefore an attractive target for the treatment of dry eye. Studies with preclinical models of dry eye disease have demonstrated that by blocking ENaC, the tear film volume is restored, maintaining its protective and lubricating actions on the ocular surface.

P-321 is the result of a comprehensive research effort to develop a potent ENaC inhibitor with unique pharmacokinetic and pharmacodynamics characteristics designed for topical ocular administration, metabolic stability and limited systemic exposure. Parion Sciences has completed all the preclinical safety and mechanistic studies required to initiate clinical studies in humans.

### **About Parion's ARVO Poster Presentation**

Parion will present preclinical data for P-321 in a poster session at ARVO. Details of the presentation are as follows:

**Title:** Ocular Pharmacokinetics of P-321, a Novel Long-Acting Epithelial Sodium Channel Blocker

**Session Name:** Poster Session #376, Dry Eye Disease #2

**Poster Number:** #A0207

**Session Date and Time:** Tuesday, May 6, 3:45 p.m. to 5:30 p.m. ET

**Session Location:** Orange County Convention Center– South Concourse, South Building

For additional information about ARVO visit <http://www.arvo.org>.

### **About Parion Sciences**

Parion Sciences is a development-stage company dedicated to research, development, and commercialization of treatments to restore patient's innate mucosal surface defenses. Parion's science driven technologies target ocular and respiratory diseases in which the patient's ability to protect their mucosal surfaces is compromised.

Parion Sciences was founded based on proprietary ENaC inhibitor technology from The University of North Carolina, Chapel Hill and has received grant funding from the National Institutes of Health and the Cystic Fibrosis Foundation Therapeutics, Inc. Today, while Parion remains at the forefront of ENaC research, the company is leveraging its research and development expertise in epithelial biology to expand into new indications and platforms that further treat additional mucosal defects. Parion is currently advancing several programs through clinical development including unique ENaC inhibitors, P-1037 for pulmonary diseases and P-321 for treatment of dry eye disease.

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