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Parion Sciences Announces Initiation of Phase 2 Clinical Trial of P-321 for the Treatment of Dry Eye Disease

-First Patient Enrolled in P-321-202 Clinical Trial

Durham, NC (July 26, 2016) – Parion Sciences, a company dedicated to the development of novel treatments for pulmonary and ocular diseases, announced today it has initiated a phase 2 clinical trial of P-321 Ophthalmic Solution in patients with Dry Eye Disease (DED). P-321 is a potent inhibitor of the epithelial sodium channels (ENaC) on the ocular surface, and is expected to restore the tear film on the ocular surface in those patients with dry eye disease. Earlier this year the results of a Phase 1/2a safety, tolerability, and pharmacokinetics study in subjects with dry eye were presented. Below is additional information on the new trial:

- Study P-321-202 is an assessment of the impact of P-321 on dry eye symptoms as well as clinical signs of dry eye disease and safety. Parion expects to enroll approximately 60 patients in the randomized, double-masked, parallel group study of P-321 Ophthalmic Solution compared to placebo in patients with dry eye disease over 28 Days. The purpose of this study is to evaluate the effect of treatment with P-321 Ophthalmic Solution on dry eye symptoms. Patient enrollment has begun and the first patient has been enrolled in the trial.
- For additional information on this study, please refer to the following link on ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02831387

"Based on the encouraging results from our P-321 phase 1/2a safety, tolerability and pharmacokinetics clinical trial which was recently presented at the 2016 Association for Research in Vision and Ophthalmology (ARVO) meeting, we are pleased to initiate this phase 2 trial," said Paul Boucher, President and CEO of Parion. "This study allows us to continue our evaluation of P-321's potential as a novel treatment for patients suffering from dry eye."

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 could be 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 pharmacodynamic characteristics designed for topical ocular administration, metabolic stability and limited systemic exposure. Parion Sciences has completed a phase 1/2a clinical study in dry eye patients. Parion's dry eye preclinical program was supported by the NIH through the National Eye Institute and the National Center for Advancing Translational Sciences (NCATS) Bridging Interventional Development Gaps (BrIDGs) program.

About Parion Sciences

Parion Sciences is a development stage biopharmaceutical company dedicated to research, development and commercialization of treatments to improve and extend the lives of patients with innate mucosal surface defense deficiencies of the eye or airway. Parion has a diverse pipeline of preclinical and clinical candidates for the treatment of these diseases via distinctive mechanisms of action and approaches. Parion is at the forefront of ENaC development and is leveraging our scientific expertise in epithelial biology to expand our platforms and novel chemical compounds into new indications to treat mucosal defects. Parion has received support and grant funding from the National Institutes of Health and the Cystic Fibrosis Foundation Therapeutics, Inc. For more information, please see our website at www.Parion.com.