Eleven Biotherapeutics Initiates Phase 1b Clinical Study of EBI-005, a Novel, Topically-delivered IL-1 Inhibitor Protein for the Treatment of Dry Eye Disease

Follows Successful Completion of Phase 1a Clinical Study

Lead Candidate from Eleven’s AMP-Rx Product Engine for First-of-a-Kind Protein Therapeutics

Cambridge, MA, December 10, 2012 – Eleven Biotherapeutics, a biopharmaceutical company designing and engineering novel and differentiated protein-based biotherapeutics, announced today that it has initiated a Phase 1b clinical trial to evaluate EBI-005, its lead ophthalmic protein product, in patients with dry eye disease. Eleven is rapidly advancing EBI-005, a rationally-designed topical protein that inhibits the IL-1 (Interleukin-1) receptor to treat ocular surface inflammatory disorders. The Phase 1b clinical study, which is expected to complete in the first half of 2013, follows the successful conclusion of the Phase 1a study of EBI-005 in recent weeks.

“Advancing the clinical development of EBI-005, our most advanced product candidate, is a significant milestone for Eleven and an important validation of our growing pipeline of engineered biotherapeutics for ophthalmic disease,” said Abbie Celniker, PhD, Chief Executive Officer of Eleven Biotherapeutics. “We have made tremendous progress in rationally designing protein therapeutics that are optimized for ocular indications of inflammatory diseases, and we believe EBI-005 is a prime example of a protein with the potential to be a game-changing product because it is applied topically and designed to effectively address both the signs and symptoms of dry eye disease.”

Eleven’s clinical development program with EBI-005 builds upon previous proof-of-concept clinical studies conducted by Reza Dana, MD, Director of the Cornea and Refractive Surgery Service at Massachusetts Eye and Ear Infirmary and one of Eleven’s founders, in which he validated that IL-1 blockade was generally safe and well-tolerated with significant improvements in both signs and symptoms of dry eye disease. Further support for the clinical advancement of EBI-005 comes from promising preclinical studies conducted by Eleven in which EBI-005 demonstrated optimal properties for the treatment of dry eye disease, including, high potency and efficacy in a mouse model of dry eye, high thermal stability and very low systemic exposure.

“A critical need remains for more effective, topically administered treatment options for patients with dry eye disease because a significant proportion of patients do not receive optimal relief of their symptoms of dry eye disease with currently-available therapies,” said Gary N. Foulks, M.D., FACS, Professor Emeritus, Department of Ophthalmology and Director of the Cornea and External Disease Service at the University of Louisville School of Medicine.

The Phase 1b clinical trial has a robust study design as a double-blind, multi-center, randomized, placebo-controlled study to evaluate two doses of EBI-005 over a six-week period in subjects with dry eye disease. The trial is expected to enroll up to approximately 80 subjects and will be conducted in approximately nine centers throughout the United States. The primary objective of the study is to determine the safety of EBI-005 and, in addition, an assessment of biological activity of EBI-005 will be measured by the Ocular Surface Disease Index (OSDI) and corneal fluorescein staining. To learn more about this trial please visit www.clinicaltrials.gov.
About Dry Eye Disease
Dry eye disease is an ocular surface inflammatory condition caused by a dysfunction of tears. The dysfunction can occur through decreased tear production or excessive tear evaporation, both of which result in drying of the eye surface (desiccating stress). The stressed ocular surface induces an inflammatory cascade regulated by IL-1. Dry eye disease affects approximately 10% of individuals between 30 to 60 years of age, and up to 15% of those over 65. Despite its prevalence and impact on quality of life, dry eye disease is under-diagnosed, under-treated, and has few safe and effective treatment options.

About EBI-005
Eleven Biotherapeutics’ lead product candidate, EBI-005, is a novel, interleukin-1 receptor antagonist currently in Phase 1 clinical development as rationally designed topical protein for the treatment of inflammatory diseases at the surface of the eye. The mechanism of action for EBI-005 was validated in a clinical proof-of-concept study in which IL-1 blockade was generally safe and well-tolerated with significant improvements in both signs and symptoms of dry eye disease. EBI-005 has been designed to have superior physical, pharmaceutical and therapeutic properties including topical ophthalmic administration for the treatment of ocular diseases including dry eye and severe ocular allergy. In preclinical studies, EBI-005 demonstrated optimal properties for the treatment of dry eye disease, such as high potency, very low systemic exposure, which minimizes the potential for adverse effects and thermal stability, providing for a room-temperature stable product.

About Eleven Biotherapeutics
Eleven Biotherapeutics creates novel and differentiated biotherapeutics: first-of-a-kind protein-based drugs with significantly improved physical, pharmaceutical, and therapeutic benefits. The company’s AMP-Rx™ product engine brings capabilities beyond conventional approaches for making protein therapeutics, opening up new territory for the products to have novel structures, enhanced biophysical properties, and more effective targeting in disease pathways. Eleven’s success is built on designing proteins ‘fit for purpose’ that are rationally designed to have ideal therapeutic characteristics and result in best-in-class biotherapeutic products for a wide range of ophthalmologic diseases, though the technology is broadly applicable outside of ophthalmology. The Cambridge, Mass.-based company was founded in 2010 by life science investors Flagship Ventures and Third Rock Ventures and world-renowned scientific experts. For more information, please visit www.elevenbio.com.

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