Auven Therapeutics Announces Positive Results from Pivotal Clinical Trial of Seciera (OTX-101) in Dry Eye Disease

Seciera demonstrated significant improvements in tear production and ocular surface inflammation

Additional pivotal Phase 3 study planned for early 2016

St. Thomas, U.S. Virgin Islands; Lausanne, Switzerland; Madison, N.J.; and Hamilton, Bermuda – **November 13, 2015** – Auven Therapeutics today announced results from its Phase 2b/3 clinical trial evaluating the safety and efficacy of Seciera (OTX-101), a novel patented nanomicellar formulation of cyclosporine for the treatment of dry eye disease.

The 455-patient randomized, double-masked, vehicle-controlled, dose-ranging study (ClinicalTrials.gov Identifier**:** NCT02254265) was conducted at 28 investigational sites in the U.S. In the study, both concentrations (0.05% and 0.09%) of Seciera demonstrated statistical superiority over placebo-vehicle for the co-primary efficacy endpoint of change from baseline at week 12 in total conjunctival lissamine green staining. The study also demonstrated superiority to placebo-vehicle in tear production and in corneal fluorescein staining (total and inferior) at week 12 for both concentrations of Seciera. Additionally, the 0.09% dose of Seciera demonstrated superiority to placebo-vehicle in a responder analysis of tear production (≥ 10 mm increase in Schirmer's test) and in central and temporal corneal staining.

Both doses of Seciera demonstrated excellent safety, comfort and tolerability profiles compared to placebo-vehicle, with more than 90% of patients in all three groups completing the 12-week study. While there was not a statistical separation for the co-primary symptom endpoint compared to placebo, a large and consistent decrease across all three treatment groups was observed over the course of the study. The 0.09% dose appeared superior to the 0.05% in several outcome measures of interest, and was well-tolerated by the study subjects.

In accordance with guidance received from the U.S. Food and Drug Administration (FDA), a single additional Phase 3 trial will be conducted in order to confirm the significant, clinically meaningful increase in tear production seen in the Phase 2b/3 trial and the large reduction in signs of ocular surface inflammation compared to placebo-vehicle. A long-term safety study will be initiated concurrently. Enrollment for both studies is planned to begin in early 2016. If these studies are successful, the submission of a New Drug Application for Seciera for the treatment of dry eye disease is anticipated in early 2017.

"Seciera, which is being developed by Auven Therapeutics, addresses a substantial and growing market opportunity in ophthalmology," said Dr. Peter B. Corr, Co-Founder and Managing General Partner of Auven Therapeutics. "Seciera appears to be the first agent to demonstrate significant improvements in measures of two distinct pathological manifestations of dry eye disease – tear production and ocular surface inflammation. The relatively early onset of positive effects on signs for Seciera, coupled with minimal application discomfort, represent very important improvements over currently available therapies."

“We are extremely pleased with the results of this pivotal investigational trial of Seciera in dry eye disease. Current estimates of the market targeted by Seciera exceed $1.2 billion in the U.S. alone. We expect that, if the product is ultimately approved for marketing, Seciera will garner a significant share of this market and perhaps even grow the market due to its unique patient-friendly characteristics,” added Stephen Evans-Freke, Co-Founder and Managing General Partner of Auven Therapeutics.

About Seciera

Seciera is a novel, investigational nanomicellar formulation of cyclosporine utilizing patent-protected proprietary technology to enhance penetration into target tissues of the eye. It is covered by patents until at least 2033. Unlike other ocular formulations of cyclosporine, Seciera is a clear, preservative-free, isotonic aqueous solution.

About Dry Eye Disease

Dry eye disease is an inflammatory ophthalmic disease that produces symptoms of discomfort, visual disturbance and tear film instability, and generally causes damage to the ocular surface. Dry eye is a chronic and often progressive disease that is one of the most common complaints to eye care professionals, and it remains a significant underserved medical need.

About Auven Therapeutics

Auven Therapeutics is a global private equity firm that acquires and pursues accelerated development of breakthrough drugs prior to licensing to commercial partners. Auven’s in-house team of senior pharmaceutical development executives establishes the preclinical, clinical, regulatory, manufacturing and commercial strategies for all its products and oversees their execution. Auven was founded in 2007 by Stephen Evans-Freke and Dr. Peter B. Corr and maintains operations in Lausanne, London, Ft. Lauderdale, New Jersey, Bermuda, and the U.S. Virgin Islands. For more information, visit www.auventx.com.

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