Auven Therapeutics Announces Completion of Enrollment in Confirmatory Phase 3 Clinical Trial of Seciera (OTX-101) for the Treatment of Dry Eye Disease

Pivotal study to confirm significant improvements in tear production and ocular surface inflammation in patients with dry eye disease, with top-line results anticipated by year-end

Seciera poised for significant commercial opportunity as a highly competitive entrant in dry eye disease market

U.S. VIRGIN ISLANDS; LAUSANNE, SWITZERLAND; FT. LAUDERDALE, FLA.; and HAMILTON, BERMUDA – August 22, 2016 – Auven Therapeutics, an international private equity company focused on accelerated development of breakthrough therapeutic drugs, today announced it has completed patient enrollment in the Phase 3 confirmatory study of Seciera (OTX-101), a novel patented nanomicellar formulation of cyclosporine for the treatment of dry eye disease.

"The results of this Phase 3 study should support the filing of global regulatory applications for the approval of Seciera for the treatment of dry eye disease," said Dr. Peter B. Corr, Co-Founder and Managing General Partner of Auven Therapeutics. "We are pleased that a key step in this study is now complete, and we look forward to releasing the top-line results by the end of this year."

The multi-center, randomized, double-blind, placebo-controlled, two-arm, Phase 3 confirmatory trial enrolled 747 patients with confirmed dry eye disease at 47 investigational sites in the U.S. The trial is designed to confirm the significant, clinically meaningful increase in the signs of dry eye disease demonstrated in the previous Phase 2b/3 study. The primary efficacy endpoint is percent of patients with 10mm improvement in tear production (as measured by the Schirmer's test) compared to placebo. Secondary endpoints include significant reduction in signs of ocular surface inflammation, as measured by conjunctival and corneal staining.

"If approved, Seciera would be the first treatment for dry eye disease to address inadequate tear production and inflammation of the ocular surface – both being well-recognized objective measures of efficacy in treating dry eye disease. Seciera has the potential to offer a new option for patients who are not responding or are intolerant to currently available therapies," said Joseph Tauber, M.D., Medical Director of Tauber Eye Center in Kansas City, Mo., and a clinical trial investigator for Seciera.

In the previous Phase 2b/3 study, Seciera demonstrated robust statistical superiority over placebo-vehicle for the co-primary efficacy endpoint of change from baseline at week 12 in conjunctival lissamine green staining, and in analyses of tear production and fluorescein corneal staining. It also demonstrated excellent safety, comfort and tolerability profiles compared to placebo-vehicle, with more than 90 percent of patients in all groups completing the 12-week study.

"Seciera is a potential best-in-class product for the treatment of dry eye disease and presents a substantial market opportunity, with an independent commercial assessment estimating the

potential for well over $1 billion in annual sales worldwide," said Stephen Evans-Freke, Co-Founder and Managing General Partner of Auven. "We have received significant interest in Seciera from potential commercial partners and are actively engaged in discussions with companies that are well-equipped to advance Seciera through regulatory submissions and a successful commercial launch."

About Seciera

Seciera is a novel nanoscale micelle formulation of cyclosporine utilizing patent-protected proprietary technology developed by Auven Therapeutics, in cooperation with our scientific collaborators, specifically to improve the ocular tissue penetration and tolerability of topical ophthalmic therapies. The micelles containing the active compound are composed entirely of inert materials and are on average less than 25 nanometers in diameter. Seciera is covered by patents until at least 2033. Unlike other ocular formulations of cyclosporine, Seciera is a clear, preservative-free, 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 an international 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 2008 by Stephen Evans-Freke and Dr. Peter B. Corr and maintains operations in Lausanne, Ft. Lauderdale, New Jersey, Bermuda, and the U.S. Virgin Islands. For more information, visit www.auventx.com.

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