



## **Auven Therapeutics Announces Initiation of Confirmatory Phase 3 Clinical Trial of Seciera (OTX-101) for the Treatment of Dry Eye Disease**

*Study to confirm significant improvements in tear production as sole primary endpoint to support regulatory filing*

*Commercial assessment confirms Seciera has the potential for \$1 billion in sales worldwide*

**ST. THOMAS, U.S. VIRGIN ISLANDS; LAUSANNE, SWITZERLAND; FT. LAUDERDALE, FLORIDA; and HAMILTON, BERMUDA – March 3, 2016 – [Auven Therapeutics](#)**, a global private equity company focused on accelerated development of breakthrough therapeutic drugs, today announced the first patient has been dosed in its Phase 3 confirmatory study of Seciera (OTX-101), a novel patented nanomicellar formulation of cyclosporine for the treatment of dry eye disease.

Following several consultations with the U.S. Food and Drug Administration (FDA), this Phase 3 trial has been designed to confirm the significant, clinically meaningful increase in tear production (as measured by the Schirmer's test) that was demonstrated in the previous Phase 2b/3 study. The large reduction in signs of ocular surface inflammation compared to placebo-vehicle seen in the Phase 2b/3 study will be one of several secondary endpoints in the Phase 3 study. Approximately 700 patients will be enrolled at 51 U.S. trial sites.

"We anticipate this trial will demonstrate conclusively Seciera's ability to offer significant improvement in tear production and decrease in ocular surface inflammation, truly objective measures of efficacy in treating dry eye disease," said Dr. Peter B. Corr, Co-Founder and Managing General Partner of Auven Therapeutics. "We believe that a successful outcome from this trial will support registration and approval of Seciera, and we look forward to announcing the top-line results during the fourth quarter of 2016."

Auven has commissioned an independent commercial assessment of Seciera including key opinion leader and third-party payor interviews. Auven believes that Seciera will be prescribed for the treatment of moderate to severe dry eye disease by a substantial portion of ophthalmologists and should achieve peak global sales in excess of \$1 billion per year.

"We believe that Seciera's efficacy in significantly increasing tear production, combined with its lack of stinging upon application and rapid onset of initial efficacy demonstrated in the previous 455-patient study, is likely to make Seciera a very important product, both clinically and commercially," said Stephen Evans-Freke, Co-Founder and Managing General Partner of Auven.

A long-term safety study of Seciera will also be initiated. On successful completion of the Phase 3 and safety studies, Auven anticipates the submission of a New Drug Application for Seciera for the treatment of dry eye disease in early 2017.

### **About Seciera**

Seciera is a novel 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, 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 2008 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](http://www.auventx.com).

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