November 8, 2022

Allysta Pharmaceuticals, Inc. Announces Completion of Enrollment in Phase 2b/3 Clinical Trial (OASIS-1) Evaluating the Efficacy and Safety of ALY688 Ophthalmic Solution in Dry Eye Disease

-Multicenter US study enrolled over 900 subjects with moderate-to-severe dry eye disease

-Topline data anticipated in Q2 2023

BELLEVUE, WA (ACCESSWIRE). Allysta Pharmaceuticals, Inc. ("Allysta") today announced that it has completed enrollment in its Phase 2b/3 trial (OASIS-1) of ALY688 Ophthalmic Solution for the treatment of dry eye disease. ALY688 Ophthalmic Solution contains ALY688, a novel first-in-class peptide with broad anti-inflammatory and corneal epithelial regenerative properties.

The OASIS-1 trial (ClinicalTrials.gov Identifier: NCT04899518) is a randomized, double-masked, vehicle-controlled study of two concentrations of ALY688 Ophthalmic Solution vs vehicle administered twice daily for 12 weeks. This multi-center US study randomized 922 subjects with moderate-to-severe dry eye disease based upon signs (staining) and symptoms (patient-reported outcomes). Qualified subjects underwent a 2-week run-in period following which, if they continued to qualify, were randomized to one of 3 arms: ALY688 Ophthalmic Solution (0.4%), ALY688 Ophthalmic Solution (1%), or Vehicle Solution. Key endpoints are improvement in corneal staining and dry eye symptoms. Additional endpoints include improvement in conjunctival staining and tear volume (Schirmer's test).

"We are grateful to the OASIS-1 study investigators, coordinators, and dry eye patients whose dedication and commitment were instrumental in the successful completion of enrollment in this multicenter pivotal study," noted Kenneth Sall MD, Medical Head of Ophthalmology at Allysta.

The Company anticipates that topline data will be announced in the second quarter of 2023.

About Dry Eye Disease

Dry eye is a common condition affecting millions of people in the US and can cause persistent eye discomfort with pain, blurry vision, and eye fatigue leading to significant impairment of quality of life and daily activities such as computer use, reading and driving. An estimated 10MM people in the U.S., suffer from moderate-to-severe dry eye. The prevalence of dry eye disease is increasing due to an aging population, living in low humidity environments, and life-style activities, such as increased screen time. In advanced cases, significant inflammation and even scarring of the eye surface can occur. The heterogeneity of dry eye patients has posed a challenge in developing effective treatments. Allysta's approach is to target multiple common underlying mechanisms, including damage to ocular surface epithelial cells and chronic inflammatory responses at the cellular and cytokine levels in order to benefit a broad range of dry eye severity and underlying etiologies.

About ALY688 Ophthalmic Solution

ALY688 Ophthalmic Solution is a novel sterile and preservative-free eye drop formulation containing ALY688 peptide, a novel first-in-class therapeutic with unique multi-modal mechanisms-of-action that include broad anti-inflammatory activity and enhancement of corneal and conjunctival epithelial regeneration.

In animal models of dry eye disease, ALY688 decreased inflammation on the ocular surface (both T cell and pro-inflammatory cytokines) and accelerated healing (re-epithelization) following corneal injury. By targeting multiple key pathways of dry eye pathogenesis, including chronic inflammation and ocular epithelial cell damage, ALY688 may offer greater success to a broad range of dry eye sufferers.

The OASIS-1 study follows upon a Phase 1/2a trial in dry eye subjects that showed dose-related improvements in a range of clinically relevant measures of dry eye signs and symptoms. These included improvements (compared with vehicle) in ocular surface staining (both corneal and conjunctival) and patient-reported symptom scales seen as early as two weeks after starting treatment. In addition, ALY688 Ophthalmic Solution was well tolerated with a low rate of post-instillation reactions, all mild and transient, with 100% of subjects completing the full dosing period.

ALY688 peptide is a potent specific adiponectin analogue that activates multiple adiponectin signaling pathways. Adiponectin is considered a unique "protective" cytokine due to its broad beneficial actions including reduction of inflammation (both at the cytokine and cellular levels) and enhancement of epithelial regeneration; it also demonstrates anti-fibrotic activity. In preclinical models, ALY688 reduced inflammation, cell injury, and fibrosis across a range of diseases, providing opportunities to develop ALY688 in multiple disease indications.

About Allysta Pharmaceuticals

Allysta is a venture-backed private clinical stage biopharmaceutical company developing first-in-class peptide therapeutics with a focus in dry eye and fibrotic diseases. Allysta's lead programs in clinical development include ALY688 Ophthalmic Solution and ALY688ER, a sustained release formulation intended for systemic applications. Visit www.allysta.com.

Company Contact:
info@allysta.com
www.allysta.com

Allysta Media Contact:
Daryll Santuray-Begonia
Allysta Pharmaceuticals
dsanturay@allysta.com