June 22, 2021

Allysta Pharmaceuticals, Inc. Announces Initiation of Dosing in OASIS-1 Phase 2b/3 Clinical Trial (ALY688-301 Study) Evaluating the Efficacy and Safety of ALY688 Ophthalmic Solution in Dry Eye

-ALY688 Ophthalmic Solution advancing to pivotal studies based upon promising clinical safety and efficacy data

-Multicenter US study to enroll subjects with moderate-to-severe dry eye

BELLEVUE, WA (ACCESSWIRE). Allysta Pharmaceuticals, Inc. ("Allysta") today announced the initiation of its OASIS-1 Phase 2b/3 trial 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 benefits.

The company recently completed a randomized, double-masked, vehicle-controlled 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 and extending to the end of the eight-week study. In addition, ALY688 Ophthalmic Solution was well tolerated with a low rate of post-instillation reaction, all mild and transient, with 100% of subjects completing the full dosing period. Based upon these promising early data, the company is advancing into Phase 2b/3 development of ALY688 Ophthalmic Solution as 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.

The OASIS-1 (ALY688-301) Trial

The OASIS-1 trial is a randomized, double-masked, vehicle-controlled study of two concentrations of ALY688 Ophthalmic Solution versus vehicle administered twice daily for 12 weeks. This multi-center US study will enroll up to 900 subjects with moderate-to-severe dry eye signs and symptoms. The company anticipates that the study will take approximately one year to complete.

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 daily activities such as computer use, reading, and driving. An estimated ~10MM people in the US, and as many as 30 million worldwide, 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. While the condition is heterogeneous with respect to causes and severity of manifestations, common underlying mechanisms include stress and damage to ocular surface epithelial cells resulting in chronic inflammation. Current treatments aim to lubricate and moisturize the eye or reduce inflammation.

About ALY688

ALY688 Ophthalmic Solution is a novel topical formulation containing ALY688 peptide that is sterile and preservative-free. By targeting key aspects of dry eye pathogenesis, including chronic inflammation and ocular epithelial cell damage, ALY688 may benefit a broader range of dry eye sufferers than current therapies. In 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.

ALY688 peptide is a potent specific agonist of the adiponectin receptor capable of activating multiple beneficial adiponectin signaling pathways. Adiponectin is considered a unique "protective" cytokine due to its broad beneficial actions including reduction of inflammation and fibrosis, and enhancement of epithelial regeneration. This provides opportunities to develop ALY688 in multiple disease indications.

Additionally, in multiple models of fibrosis, ALY688 reduced inflammation, cell injury, and fibrosis.

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 ALY688-SR, a sustained release formulation intended for systemic applications. Allysta is advancing next-generation treatments for dry eye disease and fibrosing conditions such as nonalcoholic steatohepatitis (NASH). Visit www.allysta.com.

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