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Allysta Pharmaceuticals, Inc. Announces Positive Results from its Phase 1/2a Clinical Trial of ALY688 Ophthalmic Solution in Dry Eye Disease

Will initiate a Phase 2b/3 study in 2Q 2021

Appoints Kenneth Sall, M.D. as Medical Head, Ophthalmology, to lead efforts

BELLEVUE, WA (ACCESSWIRE). Allysta Pharmaceuticals, Inc. ("Allysta") today announced the successful completion of its Phase 1/2a trial of ALY688 Ophthalmic Solution for the treatment of dry eye disease. ALY688 Ophthalmic Solution contains ALY688, a novel, first-in-class peptide with anti-inflammatory and corneal epithelial regenerative actions.

Based upon the promising safety and efficacy findings from this study, Allysta plans to accelerate development of ALY688 Ophthalmic Solution in dry eye disease and initiate a Phase 2b/3 pivotal study anticipated to begin in Q2 2021.

The ALY688-201 study

The trial was a randomized, double-masked, vehicle-controlled, study of two concentrations of ALY688 Ophthalmic Solution vs vehicle administered twice daily for 8 weeks. This US study enrolled 138 subjects with moderate to severe dry eye; all subjects completed the study with no dropouts. The study met its primary endpoint of safety (local and systemic) with both concentrations of ALY688 demonstrating excellent ocular tolerability (similar to vehicle) and with no adverse systemic effects. Blood levels of ALY688 were below the level of detection. In exploratory efficacy measures, consistent dose-related benefits (vs vehicle) were seen in both signs (corneal and conjunctival staining) and symptoms, with effects seen as early as 2 weeks and increasing through 8 weeks of treatment. Full results will be presented in a future medical conference.

"We are pleased that the results from this first-in-human study demonstrated excellent local tolerability together with preliminary efficacy findings consistent with the robust effects seen in

preclinical models," commented Henry Hsu, MD, CEO of Allysta Pharmaceuticals. "We are excited to accelerate our program and initiate a potentially pivotal study in the first half of 2021."

Financing from Morningside Venture Investments Limited ("Morningside Ventures") will continue to support the clinical development of ALY688.

Allysta appoints Dr. Kenneth Sall M.D. as Medical Head, Ophthalmology

Dr. Sall will lead the clinical development of ALY688 Ophthalmic Solution and will direct the Phase 2b/3 study. He is a Board-Certified ophthalmologist and was formerly the Medical Director of the Sall Research Medical Center in Southern California. In that capacity, he has been a Principal Investigator for over 200 clinical trials specializing in all eye indications, including many studies in dry eye disease.

About Dry Eye Disease

Dry eye is a common condition affecting millions of people in the US and causes persistent eye discomfort with pain and eye fatigue leading to impairment of daily activities such as computer use, reading and driving. While there are many causes, in all cases, chronic irritation due to deficiency in tear production or alteration in tear composition damages cells lining the ocular surface which then incites an inflammatory response that further exacerbates the condition. Current treatments aim to lubricate and moisturize the eye or reduce inflammation. An estimated ~10MM people in the U.S., and as many as 30MM worldwide, suffer from moderate-to-severe dry eye. The prevalence of dry eye disease is increasing due to an aging population and environmental conditions, such as increased screen use and low humidity. In advanced cases, significant inflammation and even scarring of the eye surface can occur.

About ALY688

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.

ALY688 Ophthalmic Solution is a novel topical formulation containing ALY688 peptide that is sterile and preservative-free. 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.

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

About Allysta

Allysta is a venture-backed clinical stage biopharmaceutical company developing first-in-class peptide therapeutics with a focus in dry eye and fibrotic diseases. Allysta's lead candidates are in clinical and late preclinical stages, supported by compelling science and pharmacology. Allysta

is advancing next-generation treatments for dry eye disease and nonalcoholic steatohepatitis (NASH). Visit www.allysta.com.

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