TearSolutions Receives FDA Orphan Drug and Fast Track Designations for Lacripep® in Neurotrophic Keratitis and Initiates Phase 2 Clinical Trial with First Patients Dosed

Charlottesville, VA - June 2, 2026 – TearSolutions, Inc. ("TearSolutions"), a clinical-stage biotechnology company developing novel ophthalmic therapeutics, today announced receiving Food and Drug Administration (FDA) Orphan Drug (ODD) and Fast Track Designations for Lacripep in Neurotrophic Keratitis (NK) and initiating a Phase 2 clinical trial with first patients dosed.

The FDA's ODD provides incentives, including tax credits for clinical testing and up to seven years of U.S. market exclusivity upon regulatory approval. The Fast Track Designation facilitates more frequent interactions with the FDA and enables a rolling review of the New Drug Application, expediting the development and review process for drugs that treat serious conditions.

NK is a rare, degenerative corneal disease characterized by a reduction or absence of corneal sensitivity and severe impairment of corneal healing, which can lead to persistent epithelial defects and vision loss.

"Receiving both Orphan Drug and Fast Track designations from the FDA is a significant milestone that underscores the unmet medical needs that still exist in neurotrophic keratitis and the potential for Lacripep to transform how this disease is treated," said Anil Asrani, Chief Executive Officer of TearSolutions. "These designations validate our approach and afford us the opportunity to work closely with the FDA to accelerate our clinical development and bring this much-needed therapeutic option to patients sooner."

About the Phase 2 Clinical Trial

The Phase 2 clinical trial is a multicenter, randomized, vehicle-controlled study to evaluate the safety and efficacy of Lacripep in subjects with neurotrophic keratitis. Approximately 54 subjects will be enrolled.

The Phase 2 clinical trial has been initiated in the United States. For more information on the study, please visit NCT07568730.

About Lacripep

Lacripep is a novel, first-in-class synthetic peptide derived from the human tear protein "lacritin". In preclinical and early studies, Lacripep's dual neurotrophic and prosecretory functions aim to resolve underlying nerve damage, reactivate physiological basal tear secretion and restore health to the corneal epithelium. Lacripep was discovered at the University of Virginia with NIH National Eye Institute funding as a naturally occurring fragment of the larger 119 AA protein, lacritin, in an unbiased screen for novel factors capable of addressing ocular surface disease.

For more information, visit our website and follow us on LinkedIn.

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