

TearSolutions, Inc. Announces Results from Phase I/II trial of Lacripep™ to Treat Primary Sjögren's Syndrome and Appoints Anil Asrani President and CEO

TearSolutions, Inc., a privately held biotechnology company focused on the development of a novel treatment for dry eye disease and based in Charlottesville, VA, announced today the successful completion and preliminary outcomes of a Phase I/II trial of Lacripep™ in Primary Sjögren's Syndrome (PSS) patients. The trial was designed to test proof of concept and optimize the design for the next planned study. PSS patients suffer from a severe and often debilitating form of dry eye disease and are known to be deficient in lacritin, a tear protein that promotes basal tearing and influences ocular surface health. Low lacritin levels are also observed in the general dry eye population. Lacripep™ is the bioactive 19 amino acid fragment of lacritin. This trial represents the largest ophthalmic trial undertaken to date in the PSS patient population and is the first clinical study conducted with Lacripep™ as the active ingredient.

Two strengths of Lacripep™ were tested and demonstrated evidence of efficacy in both a sign (inferior corneal staining) and a symptom (burning and stinging). The lower strength exhibited a highly statistically significant reduction in inferior corneal staining, that segment of the cornea recognized as the most relevant in dry eye disease, as well as a statistically significant improvement in burning and stinging. Importantly, it showed this improvement after only two weeks of dosing. Lacripep™ was well tolerated in this population and there were no serious treatment related adverse events.

TearSolutions would like to thank the patients and physicians involved in the study for their contribution to this research as well as the Sjögren's Foundation for their continued collaboration to address a significant unmet need for this patient community. The Company now plans to initiate a definitive clinical study in general dry eye as the next step towards commercialization.

Additionally, TearSolutions' Board of Directors has announced the appointment of Anil Asrani as President and CEO. Mr. Asrani comes to TearSolutions from Medtronic, a major healthcare products company. At Medtronic, Mr. Asrani spent the last 9 years advancing through positions of increasing responsibility including marketing, investor relations, business development and strategy. Prior to joining Medtronic, he spent more than a decade performing academic medical research in molecular and cellular biology. Early in his career, Mr. Asrani worked in Dr. Gordon Laurie's UVA laboratory, and was an initial investor in the Company.

Lacripep™ was patented by Dr. Laurie, a professor at the University of Virginia, based on his groundbreaking NIH funded research into the composition of human tears. He discovered lacritin and developed Lacripep™, which represents a unique treatment modality since it would be a naturally occurring protein replacement therapy to restore homeostasis in patients with dry eye. The intellectual property invented by Dr. Laurie is exclusively licensed to TearSolutions, Inc. from the University of Virginia Licensing and Ventures Group.

“This is an extremely exciting time to be joining TearSolutions,” said Mr. Asrani, “I look forward to working with the Board and the company’s management team to continue Lacripep’s™ clinical and commercial development. I am confident that Lacripep™ can not only help alleviate dry eye patients’ symptoms by addressing the underlying cause of this disease but will also create significant value for our shareholders.”