First patients enrolled in Thymosin beta-4 dry eye trial

RegeneRx Biopharmaceuticals (Rockville, Md.) has enrolled its first patients in a phase 2b/3 clinical trial with RGN-259 (Thymosin beta-4), its sterile, preservative-free eye drop formulation developed for patients with dry eye syndrome, neurotrophic keratopathy (NK), and other corneal disorders, the company said.

The double-masked, placebo-controlled trial is being conducted at 4 sites and will enroll approximately 350 dry eye patients; completion is expected by the end of the first quarter of 2016. The co-primary endpoints are assessments of total corneal staining and reduction of ocular discomfort in patients using RGN-259 compared to those using placebo. Patients will use the eye drops 4 times daily for 28 days, RegeneRx said.