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ReGenTree commences clinical study for Dry Eye Syndrome

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ReGenTree, LLC (the Company), a joint venture company between GtreeBNT and RegeneRx Biopharmaceuticals, announced that it initiated a randomized, double masked, placebo-controlled Phase 3 clinical trial (ARISE-3) for dry eye syndrome on May 10.

The objective of the ARISE-3 study is to compare the safety and efficacy of 0.1% RGN-259 eye drops to placebo for the treatment of both the signs and symptoms of dry eye syndrome. This study design is based on the results in both ARISE-1 and ARISE-2 trials previously conducted by the Company. "The trial will recruit 700 patients with dry eye syndrome at about fifteen nationwide clinical sites, including hospitals and clinics specialized in ophthalmology, and will be completed in the middle of next year," stated officials at the Company.

Dry eye syndrome is a disease where loss of homeostasis of the tear film results in pain, itching, blurry visions, dryness, etc. RGN-259 eye drops contain the active small protein, thymosin beta 4, which is naturally-occurring in tears, other body fluids, and cells. RGN-259 eye drops have wide-ranging protective, repair, and regenerative activities. Such multifunctional activities underlie the efficacy of RGN-259 eye drops in both the signs and symptoms of dry eye. Furthermore, RGN-259 eye drops are safe and well-tolerated by the patients, and in both ARISE-1 and ARISE-2, patients reported minimal ocular discomfort on instillation that was similar to that of the placebo.