

## GtreeBNT gets patent for new ophthalmic formulation

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RegeneRx Biopharmaceuticals (RegeneRx"), a clinical-stage drug development company focused on tissue protection, repair and regeneration, reported that its U.S. joint venture partner and Pan Asian licensee, GtreeBNT, has been granted a new U.S. patent for a method of preventing or treating dry eye syndrome by administering T?4 with non-active ingredients to provide improved pharmacodynamics. T?4 is the active component of RGN-259, currently in separate phase 3 clinical trials for dry eye syndrome and neurotrophic keratitis. The expiry of this new patent is 2035.

"We are pleased that Gtree has been granted another patent related to T?4 in the ophthalmic field emanating from its comprehensive development of RGN-259, our sterile, preservative-free eye drop solution. New intellectual property, such as patents and know-how developed under our licenses to Gtree and our U.S. joint venture, ReGenTree LLC, expands and extends the IP portfolio underlying these licenses," stated J.J. Finkelstein, president and chief executive officer.

Dry eye syndrome is a common condition affecting millions of people throughout the world. It is a multi-factorial disorder where loss of homeostasis of the tear film results in pain, itching, blurry vision, and dryness, among other symptoms. RGN-259 eye drops contain an active small protein, thymosin beta 4, which is naturally occurring in tears and other body fluids. RGN-259 eye drops have demonstrated wide-ranging and multifunctional activities. Such activities underlie the efficacy of RGN-259 eye drops seen to date in alleviating both the signs and symptoms of dry eye.

RGN-259 eye drops are safe and well-tolerated by patients, and in both ARISE-1 and ARISE-2 clinical trials, patients reported minimal ocular discomfort similar to that of the placebo. RGN-259 is currently the subject of a 700-patient phase 3 clinical trial in the U.S, ARISE-3.