NT-501 Granted Orphan-Drug Designation for Macular Telangiectasia Type 2 (MacTel)

July 24, 2012, Cumberland, RI – Neurotech Pharmaceuticals, Inc., a clinical stage biotech company, announced today that the Food and Drug Administration (FDA), Office of Orphan Products Development and Drug Administration has granted orphan-drug designation of NT-501 (allogenic retinal epithelial cells transfected with plasmid vector expressing ciliary neurotrophic growth factor) for the treatment of macular telangiectasia type 2 (MacTel).

The FDA's Orphan Drug Designation program provides orphan status to drugs defined as those intended for the treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States. Orphan drug designation qualifies the sponsor of the drug for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.

The Orphan Drug Designation highlights Neurotech's potential to bring safe and effective care to patients with MacTel Type2.

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About Macular Telangiectasia Type 2 (MacTel)
Macular telangiectasia type 2 (MacTel), or idiopathic juxtafoveal macular telangiectasia type 2, is a rare neurodegenerative disease with characteristic alterations of the retinal vasculature and localized retinal degeneration.[1] MacTel typically affects both eyes and causes a gradual deterioration in central vision.

About NT-501 Implant

Designed to be implanted into the vitreous cavity of the eye, the investigational NT-501 implant is a tiny hollow cylindrical membrane which encapsulates human epithelial cells genetically engineered to produce ciliary neurotropic factor (CNTF) continuously, a protein now clinically validated in Phase 3 clinical trials to slow the progression of MacTel.

About Encapsulated Cell Therapy

Encapsulated Cell Therapy (ECT) is an investigational first-in-class, platform technology that promotes continuous production of therapeutic proteins to the eye with the potential to treat a broad array of ocular diseases. It utilizes a proprietary, well-characterized retinal pigment epithelial cell line that has been genetically engineered to produce therapeutically active biologics. The cells are encapsulated in a semi-permeable membrane that allows for selective passage of therapeutic proteins. The ECT platform is inserted during a single outpatient surgical procedure through a small scleral incision, and can also be removed through the same incision, if desired. ECT has the potential to address the current limitations of intraocular drug delivery by allowing for and ensuring patient compliance and reducing treatment burden with one surgical procedure that can deliver drug for at least 2 years.

About Neurotech Pharmaceuticals, Inc.

Neurotech Pharmaceuticals, Inc. is a private clinical stage biotech company focused on developing transformative therapies for chronic eye diseases. The core platform technology, Encapsulated Cell Therapy (ECT), enables continuous production of therapeutic proteins to the eye. Neurotech is currently studying in the clinic ECT candidates to treat Macular telangiectasia type 2 and glaucoma. To learn more, visit https://www.neurotechpharmaceuticals.com/.

1. Charbel Issa P, Gillies MC, Chew EY, Heeren TFC, Bird AC, Peto T, Holz FG, Scholl HPN (2013) Macular Telangiectasia Type 2. Prog. Retin. Eye Res. 34: 49-77.

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