Neurotech Provides Update on BLA for NT-501 as a Treatment for Macular Telangiectasia Type 2 (MacTel)

Cumberland, R.I., November 8, 2024 (BUSINESS WIRE) – Neurotech Pharmaceuticals, Inc., an innovator in sustained drug delivery for chronic retinal diseases, today announced that the U.S. Food and Drug Administration (FDA), has extended the Prescription Drug User Fee Act (PDUFA) goal date by three months to allow time required for the FDA to review additional data provided by the Company in response to recent requests from the FDA. The new PDUFA goal date for the biologics license application (BLA) of NT-501 (revakinagene taroretcel) as a treatment for Macular telangiectasia type 2 (MacTel) is March 18, 2025.

“We are committed to providing the Agency any information needed to complete the review of the NT-501 BLA,” said Richard Small, Chief Executive Officer. “Neurotech will continue in our effort to bring this important therapy to MacTel patients.”

About Macular Telangiectasia (MacTel)

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

About Encapsulated Cell Therapy (ECT)

The ECT platform is a cell-based delivery system designed to provide long-term, sustained delivery of therapeutic proteins for the treatment of chronic retinal diseases. This versatile platform consists of a small, semi-permeable capsule containing proprietary allogeneic retinal pigment epithelium (RPE) cells genetically engineered to produce specific therapeutic proteins for targeted disease treatment. The capsule is surgically inserted into the patient’s vitreous and sutured to the sclera during an outpatient procedure. Once in place, the capsule's semi-permeable membrane allows essential nutrients to enter, while also permitting the therapeutic proteins to exit into the vitreous, providing targeted and continuous treatment. Simultaneously, the membrane protects the encapsulated RPE cells from the host's immune system, ensuring their long-term survival and functionality.

About NT-501 Implant

NT-501 leverages our ECT platform to deliver CNTF for the treatment of chronic retinal diseases, such as MacTel. CNTF is a potent neuroprotective protein that promotes the survival and maintenance of photoreceptors. This targeted therapy provides sustained delivery of CNTF, aiming to slow retinal degeneration and potentially improve long-term visual outcomes for patients.

About Neurotech Pharmaceuticals, Inc.

Neurotech Pharmaceuticals, Inc. is a private, clinical stage biotechnology company and an innovator in sustained drug delivery for chronic retinal diseases. The core platform technology, ECT, enables continuous production of therapeutic proteins to the back of the eye. For more information about us, please 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.

Corporate Contact:
Laurie Ferguson, Chief Communications Officer
Phone: 401-556-8649
Email: l.ferguson@neurotechusa.com