Neurotech Pharmaceuticals, Inc. Receives Priority Review of Biologics License Application (BLA) for NT-501 (revakinagene taroretcel) as a Treatment for Macular Telangiectasia Type 2 (MacTel)

June 20, 2024

- Priority review granted with a PDUFA goal date set for December 17, 2024.

Cumberland, R.I., June 20, 2024 – Neurotech Pharmaceuticals, Inc., an innovator in sustained drug delivery for chronic retinal diseases, announces that the U.S. Food and Drug Administration (FDA), has determined that the Biologic License Application (BLA) for NT-501, an investigational encapsulated cell therapy for the treatment of MacTel, is sufficiently complete to permit a substantive review. The application has a prescription drug user fee act (PDUFA) goal date of December 17, 2024.

MacTel is a progressive, neurodegenerative disease of the retina that results in the deterioration of central vision, significantly impacting patients' quality of life. NT-501 is an ocular implant designed to deliver sustained therapeutic doses of ciliary neurotrophic factor (CNTF) directly to the retina to slow the progression of the disease.

“This is a significant achievement for Neurotech,” said Richard Small, Chief Executive Officer. “I would like to express my gratitude to our employees for reaching this important milestone.”

About Macular Telangiectasia (MacTel)

MacTel, or idiopathic juxtafoveal macular telangiectasia, is a rare neurodegenerative disease with characteristic localized retinal degeneration with secondary alterations of the retinal vasculature.[1] MacTel typically affects both eyes and causes deterioration in central vision impacting patients' quality of life.

About Encapsulated Cell Therapy (ECT)

The ECT platform is a cell-based delivery system that was 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 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.

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