

Neurotech Announces FDA Acceptance of Investigational New Drug Application and Clinical Trial Initiation of Novel Therapy for Wet AMD

Efficacy and Safety of Long-term, Continuous Anti-VEGF will be Assessed in Phase 2 Study

March 30, 2015, Cumberland, RI – Neurotech Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted and communicated Neurotech's ability to proceed with its Investigational New Drug (IND) application to conduct a Phase 2 clinical study of NT-503 Encapsulated Cell Therapy (ECT) for the treatment of recurrent subfoveal choroidal neovascularization secondary to age related macular degeneration (wet AMD).

The Phase 2, randomized, active-controlled, masked study will commence immediately and enroll 150 patients. The safety and efficacy of one NT-503 ECT implant will be compared to aflibercept intravitreal injections every 8 weeks in patients who have been treated with at least 3 anti-VEGF injections and still have active disease. Patients will be followed for 2 years with a 12-month interim assessment.

“We are delighted to be a part of this important study,” expressed study investigator David Boyer, MD, Senior Partner at Retina-Vitreous Associates Medical Group and Clinical Professor of Ophthalmology at the University of Southern California Keck School of Medicine. “The NT-503 ECT implant, essentially a reversible gene therapy, represents the future of intraocular drug delivery. To have a therapy that could effectively and continuously treat our AMD patients long-term without the burden of frequent injections is very exciting. It is also advantageous to have the option of removing the implant, if desired.”

ECT is an intravitreal implant that houses a proprietary retinal pigment epithelial cell line genetically engineered to produce several therapeutically active biologics for at least 2 years. NT-503 is a novel vascular endothelial growth factor (VEGF) receptor protein that is continuously produced by the ECT platform.

“This is a significant milestone for our NT-503 ECT program,” commented Quinton Oswald, Chief Executive Officer of Neurotech. “Real-world injection frequencies often do not correlate with optimal treatment recommendations due to the enormous burden of monthly or bi-monthly injections and disease monitoring,” he added. “We are one step closer to being able to give patients and physicians an efficacious, long-term therapy with a single outpatient surgical procedure.”

About Neovascular Age Related Macular Degeneration

Neovascular or “wet” age related macular degeneration is the most advanced stage of AMD. It involves the growth of new, abnormal blood vessels (promoted by VEGF), and typically results in severe vision loss. Almost 2 million patients in the U.S. have advanced AMD, and it is the most common cause of blindness in those over the age of 55. While there is no cure, current standard of care is aimed at treating vision loss and the associated leakage of fluid from the abnormal blood vessels through the routine administration of anti-VEGF intravitreal injections.

Anti-VEGF injections have dramatically improved visual outcomes in patients with wet AMD. However, these improvements are dependent upon frequent injections and close monitoring, which places a large burden on patients, physicians, caregivers, and the healthcare system. As such, studies have shown that real world utilization rates of anti-VEGF injections are often sub-optimal, and alternative approaches intended to reduce the treatment burden, including “as needed” regimens, are sometimes less effective than monthly or bi-monthly administration. A long-term, continuous therapy with a low treatment burden remains a clear unmet need in wet AMD treatment.

About Encapsulated Cell Therapy

Encapsulated Cell Therapy is an investigational, first in class, versatile delivery system 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 3 mm 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 single- and multiple-factor drug combinations 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 biotechnology company focused on developing transformative therapies for chronic eye diseases. The core technology platform, Encapsulated Cell Therapy, enables continuous production of therapeutic proteins to the eye. Neurotech is exploring several ECT candidates, including its lead product for the treatment of wet AMD (NT-503), combination therapies for wet AMD, treatments for other forms of retinal degeneration, uveitis, and glaucoma. To learn more, visit www.neurotechusa.com.

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