

## **Neurotech Announces First Patient Enrolled in Novel Anti-VEGF Encapsulated Cell Therapy Study**

September 2, 2015, Cumberland, RI – Neurotech Pharmaceuticals, Inc., announced today the first patient has been enrolled in the multicenter Phase 2 clinical trial of NT-503 Encapsulated Cell Therapy (ECT) for the long-term treatment of recurrent subfoveal choroidal neovascularization secondary to age related macular degeneration (wet AMD). NT-503 is a unique vascular endothelial growth factor (VEGF) receptor protein continuously produced by Neurotech’s versatile ECT implant.

“This landmark proof-of-concept study will evaluate NT-503 ECT as a viable alternative to frequent intravitreal injections in wet AMD patients,” said Charles Johnson, MD, Chief Medical Officer. “We believe NT-503 ECT has the potential to maintain visual acuity in patients who have already exhibited a good response to intravitreal injections, while reducing the long-term treatment burden. This program will provide key information regarding the safety and efficacy of NT-503 ECT as we continue to make progress toward our goal of advancing treatment for wet AMD and other chronic posterior segment conditions.”

The Phase 2 randomized, active-controlled, masked study will evaluate the safety and efficacy of NT-503 ECT compared to aflibercept (Eylea®) intravitreal injections. Approximately 150 patients who have previously been treated with at least 3 anti-VEGF injections and have demonstrated a good clinical response will be enrolled. This study will compare maintenance of vision in patients randomized to receive a single NT-503 ECT implant or aflibercept injections every 8 weeks. Efficacy will be evaluated using a combination of endpoints including: change in visual acuity, change in retinal thickness, rate of treatment failures, and rate of rescue medication. A primary analysis will be conducted at one year and patients will be followed for two years.

“We are very excited to initiate this study,” said Arshad Khanani, MD, Managing Partner of Sierra Eye Associates in Reno, Nevada, the first retinal surgeon to enroll a patient in the trial. “ECT represents the future of drug delivery. It has the capability to allow for the continuous delivery of therapeutics with a single surgical procedure. NT-503 ECT has the potential to maintain a therapeutic response in patients with wet AMD while eliminating the need for repeated injections.”

Neurotech anticipates enrollment to be completed by the end of 2015 and plans to report top-line data from their Phase 2 program in the first half of 2017.

## **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 vascular endothelial growth factor or VEGF), and typically results in severe vision loss. Almost 2 million patients in the U.S. have wet 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 abnormal blood vessels through the routine administration of intravitreal anti-VEGF injections.

Anti-VEGF injections have dramatically improved visual outcomes in patients with wet AMD. However, 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 and NT-503**

Encapsulated Cell Therapy is an investigational, first-in-class, versatile delivery platform that promotes continuous production of therapeutics 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 implanted during a single outpatient surgical procedure through a small scleral incision and can be removed through the same incision, if desired. It 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.

To date more than 280 patients have received ECT with either the NT-501 (CNTF) or NT-503 (sVEGF) producing constructs. Adverse events have been generally mild and consistent with those expected from the surgical procedure or the secreted protein.

Neurotech’s lead clinical product, NT-503 ECT, continuously produces a soluble vascular endothelial growth factor receptor protein. Dose-escalation studies with NT-503 ECT have been successfully conducted in patients with wet AMD.



### **About Neurotech Pharmaceuticals, Inc.**

Neurotech Pharmaceuticals, Inc. is a private biotechnology company focused on developing transformative therapies for chronic eye diseases. Its 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, DME and RVO (NT-503), combination therapy for wet AMD (NT-506), and ciliary neurotrophic factor (NT-501) for glaucoma and macular telangiectasia (MacTel). To learn more, visit [www.neurotechusa.com](http://www.neurotechusa.com).