First Patients Enrolled in Groundbreaking Brain Cancer Study at Nationally Recognized Academic Medical Center

Exvade Bioscience today announced it has enrolled its first patients in a Phase 1 Trial at the Preston Robert Tisch Brain Tumor Center at Duke University.

REDMOND, WA, UNITED STATES, November 25, 2025 / EINPresswire.com/ -- Exvade Bioscience, a clinical-stage neuro-oncology company redefining how aggressive brain cancers are monitored and treated, today announced it has enrolled its first patients in a Phase 1 Trial (NCT04547777) at the Preston Robert Tisch Brain Tumor Center at Duke University, with early results indicating a favorable safety profile for Exvade's Tumor Monorail Device (TMD) - an FDA Breakthrough Device designed to give physicians safe, real-time access to brain tumors and their evolving microenvironment throughout treatment.

The End Brain Cancer Initiative (EBCI) has partnered with Exvade Bioscience to promote awareness of and pre-qualify patients for this trial. Patients who would like to learn more and see if they qualify can visit https://endbraincancer.org/exvade-bioscience/ or contact EBCI's Clinical Research Coordinator and Patient Navigator, Shreya Prakash, at Shreya@EndBrainCancer.org or 425-436-8688.

The trial marks the first-ever use of a bio-inspired implant that not only guide invasive brain-tumor cells away from critical brain regions toward a designated 'safe zone', outside of the brain, but also enables repeated, minimally invasive sampling of live tumor tissue – once thought unattainable in glioblastoma (GBM), one of the most aggressive and treatment-resistant brain

cancers. By doing so, Exvade is tackling a challenging barrier to effective GBM therapies - the current inability to dynamically assess tumor response to therapy without repeat surgeries.

Using TMD for longitudinal sampling of tumor provides safe access to heterogenous tumor tissue through a simple outpatient procedure-akin to a blood draw- unlike standard brain tumor needle biopsy, which requires a full surgical intervention that comes with risks of infection and bleeding

The Phase 1 study is enrolling adults with recurrent glioblastoma (GBM) who have undergone prior standard therapy to evaluate a novel dual approach that combines two investigational immunotherapies (D2C7-IT and 2141-V11) with advanced tumor monitoring using Exvade's TMD. The surgically implanted catheter system is placed at the tumor site and remains in place throughout treatment, enabling continuous monitoring of tumor evolution and response to treatment. The trial includes two key components: one focused on evaluating the safety and feasibility of the TMD for monitoring tumor during treatment in adult patients with recurrent glioblastoma, and the other - testing a combination therapy that delivers two experimental drugs, D2C7-IT in combination with an Fc engineered Anti-CD40 Monoclonal Antibody, directly into the tumor and surrounding tissue to target cancer cells more precisely.

D2C7-IT is an investigational immunotoxin designed to target and bind to both wild-type EGFR and EGFRvIII, two proteins frequently overexpressed in glioblastoma cells. This targeted therapy is intended to destroy tumor cells while minimizing damage to healthy brain tissue. D2C7-IT is administered in combination with 2141-V11, a fully-human anti-CD40 agonist antibody, which potentiate the immune response from the tumor breakdown initiated by D2C7-IT.

In this study, the TMD is first inserted in proximity to the tumor recurrence, after which, D2C7-IT and 2141-V11 are administered directly into the intracerebral tumor using convection-enhanced delivery (CED)—a method that bypasses the blood-brain barrier to allow high concentrations of drug to reach tumor-infiltrated regions, after which, patients undergo repeated dosing of 2141-V11 subcutaneously in the upper neck area (cervical perilymphatic area). The initial intracerebral administration of D2C7-IT and 2141-V11 is intended to initiate a tumor breakdown and immune activation, while the repeated dosing of 2141-V11 in the cervical perilymphatic area aims to maintain a strong immune response. The TMD is accessed by subcutaneous needle aspiration at each dosing of the 2141-V11 in the cervical perilymphatic area, allowing real time evaluation of the tumor status.

"By allowing real-time monitoring of the tumor over time, while on therapy, we will hopefully be able to more swiftly identify the degree of efficacy or the limitations of our therapies, while preventing the trauma and costs of repeated brain surgery," said Dr. Annick Desjardins, MD, FRCPC, neuro-oncologist, professor of neurosurgery and neurology at Duke University and the study's principal investigator.

"Serial tumor sampling remains one of the most critical unmet needs and perhaps the holy grail

in GBM research and drug development," said Nassir Mokarram, co-founder of Exvade Bioscience and co-inventor of TMD. "Currently most trials are challenged to confirm whether drugs reach the tumor, trigger meaningful biological changes, or overcome resistance to current therapies. We believe an effective treatment for many glioblastoma patients may exist – we just need a way to provide clinicians with timely, accurate and actionable insight into the tumor and its microenvironment. Tumor Monorail could dramatically accelerate the pace at which new treatments are validated, optimized and personalized for patients."

Eligibility Criteria Include:

- Adults aged 18 or older with histologically confirmed recurrent glioblastoma
- Tumor recurrence after prior standard therapy (surgery, radiation, chemotherapy)

This study represents a paradigm-shifting step toward more personalized and precise treatment of brain tumors.

To learn more about the study and eligibility, visit the official clinical trial listing: https://clinicaltrials.gov/study/NCT04547777

About Glioblastoma

Glioblastoma is the most common and devastating primary malignant brain tumor in adults. With an incidence of approximately 3.2 per 100,000 population in the USA, approximately 12,300 people are diagnosed with a glioblastoma yearly. Standard of care for the treatment of glioblastoma is typically 'maximal safe' surgical resection followed by radiotherapy plus concomitant and maintenance temozolomide chemotherapy with or without the Optune® device. There is currently, no standard of care treatment at the time of tumor recurrence, which leads to a median survival from initial diagnosis of less than 21 months.

About Exvade Bioscience

Exvade Bioscience is a clinical-stage biotechnology company pioneering advanced technologies that create a path of least resistance for tumor migration - enabling easier sampling, potentially protecting critical tissues from invasion, and ultimately redirecting tumor cells to where they can be eliminated with targeted therapies. By providing clinicians with safe, real time access to tumor tissue throughout treatment without the need for multiple surgeries with the Tumor Monorail Device, Exvade aims to transform the way aggressive cancers like glioblastoma are understood and treated. The company's approach enables dynamic, personalized data-driven intervention strategies designed to stay ahead of tumor evolution, drug resistance, and recurrence. Exvade is committed to advancing precision medicine in neuro-oncology and other hard-to-treat cancers¬, enabled by generous funding from the Marcus Foundation and NIH SBIR Program. Learn more at exvadebio.com

About the End Brain Cancer Initiative

To support/donate to the End Brain Cancer Initiative's increased access and health delivery for

patients, mission, services and programs, please visit EndBrainCancer.org

The End Brain Cancer Initiative (EBCI) is a 501(c)3 non-profit patient advocacy organization focused on disease education, awareness, outreach, increasing patient access and improving Standard of Care. The End Brain Cancer Initiative, formerly known as the Chris Elliott Fund (CEF), is dedicated to ensuring that all patients diagnosed with brain cancer, a brain tumor, or metastatic disease to the brain have equal access to advanced diagnostics, treatments, specialists, and clinical trial participation. We believe that IMMEDIATE ACCESS to these options provides this patient community with the best HOPE for survival and sustained quality of life. We partner with industry, patients, researchers, advocacy groups, medical teams, hospital networks and others to educate patients and their caregivers so they can have empowered conversations with their medical teams. Learn more about the End Brain Cancer Initiative or how to sponsor this annual campaign at EndBrainCancer.org.

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