September 4, 2024

Adaptin Bio Announces FDA Clearance of IND Application for APTN-101 in Glioblastoma

- APTN-101 is a novel BRiTE therapeutic targeting the most aggressive form of brain cancer
- Unique mechanism of action of APTN-101 will be evaluated in Phase 1 first-in human clinical trial in glioblastoma

CHARLOTTE, N.C.--(BUSINESS WIRE)-- Adaptin Bio, a biotechnology company focused on developing precision cancer therapies with improved delivery to the brain and other tissues, has emerged from stealth today with the announcement that FDA has cleared an Investigational New Drug (IND) application for its APTN-101 program in glioblastoma (GBM), the most common and aggressive primary brain tumor. The clearance will enable the initiation of a first-in-human Phase 1 clinical trial to evaluate this investigational candidate in GBM.

APTN-101 is a proprietary BRiTE (Brain Bispecific T cell Engager) therapeutic designed to target EGFRvIII, a specific protein linked to aggressive brain tumors. In preclinical studies, APTN-101 has shown a greater than 7-fold increase in distribution into the brain, with significant potential in eradicating malignant glioma tumors as a potentially best-in-class therapy. The Phase 1 clinical trial will assess the safety and efficacy of APTN-101 in patients diagnosed with WHO Grade IV Malignant Glioma, also known as GBM.

Current treatment options for GBM include surgery, radiotherapy, and chemotherapy, which aim to remove or destroy tumor cells within the brain but fail to completely eliminate the disease due to its invasive nature. GBM deeply infiltrates the brain and despite aggressive treatment, residual tumor cells often lead to disease recurrence. GBM represents one of the most aggressive and challenging forms of brain cancer, with a median survival rate of just 12-18 months post-diagnosis, with only 5% of patients surviving beyond five years. The disease accounts for approximately 15,000 new cases per year in the US. Secondary malignant brain tumors account for about 200,000 new cases annually. This critical unmet need demands innovative therapies that can overcome the limitations of current treatments that do not cross the blood brain barrier.

“The FDA clearance is a significant achievement for our collaboration with Adaptin. Based on results from preclinical models in orthotopic malignant glioma, we are excited to begin this clinical trial to evaluate the safety and efficacy of APTN-101,” said Mustafa Khasraw, M.D., Professor of Neurosurgery, Medicine, Integrative Immunobiology, Cancer Biology and Pharmacology at Duke University. “APTN-101’s ability to cross the blood-brain barrier and target glioma cells directly offers a promising new approach.”

“We’re thrilled to initiate clinical trials with APTN-101 following FDA clearance of our first-in-human trial,” said Michael J. Roberts, Ph.D., CEO, Adaptin Bio. “Our proprietary BRiTE technology harnesses the immune system’s remarkable ability to target and deliver

therapeutics to specific tissues, including the brain, potentially revolutionizing treatment for difficult-to-treat cancers. APTN-101 validates the BRiTE platform and its ability to enhance transfer of therapeutics into the brain. We are committed to advancing this novel therapy as a new potential therapy for glioblastoma patients who desperately need new therapies."

"Adaptin's innovative delivery technology has the potential to revolutionize treatment for cancer and central nervous system disorders. We are proud to support Adaptin Bio as part of our ongoing commitment to partnering with visionary entrepreneurs and translating groundbreaking technologies from leading academic institutions into impactful solutions," said James Ahern, Managing Partner of Laidlaw & Company and Founding Partner of Lucius Partners, who is an investor in Adaptin Bio.

In preclinical studies, APTN-101 has shown impressive efficacy in eliminating malignant glioma tumors across various aggressive orthotopic models. The BRiTE platform, developed by researchers in the Department of Neurosurgery at Duke University under the leadership of Dr. John H. Sampson, harnesses the ability of T cells to precisely target and destroy glioma cells while effectively navigating the brain's unique environment.

Adaptin Bio's proprietary BRiTE technology leverages the enhanced "hitchhiking" capabilities of manipulated immune cells to deliver therapeutic agents directly to brain tumors. This innovative approach has demonstrated high specificity for EGFRvIII expressing glioma cells, dose-responsive efficacy against diverse patient-derived glioma cell lines, and a favorable safety profile. Additional BRiTE targets are being evaluated. By manipulating the immune system either in vivo or ex vivo, BRiTE aims to overcome traditional treatment barriers and offer a promising new therapeutic option for patients with intracerebral malignancies.

About Adaptin Bio

Adaptin Bio is a biotechnology company developing novel therapies for oncology and central nervous system disorders with improved drug delivery to the brain and other tissues. The company's proprietary Brain Bispecific T cell Engager (BRiTE) technology was developed by researchers at the Department of Neurosurgery at Duke University. The company's mission is to develop novel therapies to improve patient outcomes in difficult-to-treat cancers. For more information, visit www.adaptinbio.com.

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Source: Adaptin Bio