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# Adaptin Bio Advances Novel Brain Cancer Treatment Candidate Towards Phase 1 Glioblastoma Clinical Trial

**The Preston Robert Tisch Brain Tumor Center grants first IRB approval for APTN-101's Phase I clinical trial, enabling patient recruitment to begin**

**APTN-101, the Company's Brain Bispecific T cell Engager (BRiTE), yields precise and potent anti-tumor activity by redirecting T cells to bind and destroy cancer cells in the brain**

**Dose-response efficacy and favorable safety profile observed by Duke University scientists in preclinical studies**

CHARLOTTE, N.C., Jan. 20, 2026 (GLOBE NEWSWIRE) -- Adaptin Bio, Inc. ("Adaptin" or the "Company"), a biotechnology company developing precision cancer therapeutics enabled by targeted delivery to the brain and other difficult-to-reach tissues, today announced that the Preston Robert Tisch Brain Tumor Center has granted the first Institutional Review Board (IBRB) approval for the Company's Phase 1 first-in-human clinical trial evaluating APTN-101 in the treatment of glioblastoma multiforme (GBM).

"Following the successful preclinical development and acceptance of our Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA), we are extremely pleased to receive our first IRB approval for APTN-101's Phase I clinical trial," said Michael J. Roberts, Ph.D., Chief Executive Officer of Adaptin Bio. "This represents a major inflection point for our lead program and validates the translation readiness of our targeted bispecific antibody platform. In collaboration with Duke University investigators, the inventors of our BRiTE platform, APTN-101 demonstrated compelling anti-tumor activity and a favorable safety profile in multiple preclinical models. With clinical, manufacturing, and regulatory foundations now in place, we are positioned to advance APTN-101 into the clinic and work toward delivering a meaningful new therapeutic option for patients facing a devastating disease."

Glioblastoma multiforme, classified as a World Health Organization (WHO) Grade IV malignant glioma, is the most aggressive and lethal primary brain tumor. Despite decades of research, standard-of-care treatment (surgical resection followed by radiation and chemotherapy) remains largely palliative, with median survival of approximately 14–16 months and five-year survival rates below 10%. More than 12,000 new cases are diagnosed annually in the United States alone, underscoring the urgent unmet medical need for innovative therapeutic approaches. A primary obstacle to progress in GBM and other central nervous system (CNS) diseases is the blood-brain barrier (BBB), which prevents most biologics and immune therapies from reaching therapeutic concentrations within the brain, severely limiting their clinical efficacy.

Adaptin's BRiTE (Brain Bispecific T cell Engager) platform is designed to overcome this fundamental limitation by enabling efficient and selective delivery of immune-engaging biologics across the BBB. APTN-101 leverages this platform to transport a potent T-cell–redirecting bispecific antibody into the brain, where it can recruit and activate cytotoxic T cells directly at the tumor site. By enabling immune effector cells to penetrate the CNS and engage malignant cells in situ, APTN-101 is designed to address both the immune-privileged nature of the brain and the infiltrative biology of GBM, offering the potential for deeper, more durable anti-tumor responses than existing therapies.

Beyond glioblastoma, Adaptin believes its BBB-penetrant immune delivery approach has broad applicability across multiple CNS oncology and neurology indications, representing estimated billion-dollar-plus market opportunities. The global glioma treatment market alone is projected to reach approximately $4.4 billion, with significant expansion potential as effective targeted and immunotherapeutic strategies become clinically viable. Adaptin plans to leverage the BRiTE platform to build a pipeline of brain-directed immunotherapies aimed at transforming outcomes for patients with currently intractable CNS diseases.

**About APTN-101 BRiTE Therapeutic**

Adaptin Bio's proprietary brain bispecific T cell engager, APTN-101, leverages the enhanced "hitchhiking" capabilities of manipulated immune cells to deliver therapeutic agents directly to brain tumors. The novel 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. 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, Inc.**

Adaptin Bio, Inc. is a biotechnology company developing novel therapies for oncology and central nervous system disorders. Its mission is to improve patient outcomes in difficult-to-treat cancers by improving and enhancing drug delivery to the brain and other tissues. The Company's proprietary Brain Bispecific T cell Engager (BRiTE) technology, powering investigational cancer therapeutic APTN-101, was developed by researchers at the Department of Neurosurgery at Duke University. APTN-101 is FDA-cleared for a Phase 1 clinical trial in glioblastoma (GBM), and other indications are being considered for future studies. For more information, visit www.adaptinbio.com.

**Caution Regarding Forward Looking Statements:**

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. These forward-looking statements may include information concerning possible or projected future business operations. Such statements are often characterized by the use of qualified words (and their derivatives) such as "anticipate," "believe," "continues," "could," "design," "estimate," "expect," "goals," "intend," "looking," "may," "objectives," "opportunity," "outlook," "plan," "positioned," "potential," "project," "seek," "should," "target," "will," "would," or other statements concerning opinions or judgments of the Company and its management about future events. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: our ability to raise additional money to fund our operations for at least the next 12 months as a going concern and develop our product candidate as anticipated; our

ability to control costs associated with our operations; intellectual property risks; risks of our clinical trials, including, but not limited to, the timing, delays, costs, design, initiation, enrollment, and results of such trials; any delays in regulatory review and approval of product candidates in development; reliance on third parties to supply drug substance and drug product for our clinical trials and preclinical studies, and produce commercial supplies of product candidates; the potential advantages of our product candidate; our competitive position; risks related to our potential quotation on the OTC Markets and ability to develop a market for common stock; our ability to maintain our culture and recruit, integrate and retain qualified personnel and advisors, including on our Board of Directors; volatility and uncertainty in the global economy and financial markets; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and other risks and uncertainties set forth from time to time in our filings with the Securities and Exchange Commission. Adaptin assumes no obligation and does not intend to update these forward-looking statements except as required by law.

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