

BrainChild Bio Initiates Pivotal Phase 2 Trial for BCB-276 CAR T cell Therapy for DIPG, a Deadly Pediatric Brain Cancer

ILLUMINATE Phase 2 pivotal study will enroll patients at six leading pediatric oncology centers across the U.S.

B7-H3-targeted autologous CAR T cell therapy offers new treatment for diffuse intrinsic pontine glioma (DIPG), an aggressive brainstem tumor with limited treatment options

SEATTLE & CAMBRIDGE, Mass. – September 8, 2026 – [BrainChild Bio, Inc.](#), a clinical-stage biotechnology company developing CAR T cell therapies to treat tumors in the central nervous system, today announced the initiation of a pivotal Phase 2 clinical trial to evaluate BCB-276, its investigational B7-H3-targeted autologous CAR T cell therapy, for the treatment of diffuse intrinsic pontine glioma (DIPG), a rare and aggressive pediatric brainstem tumor with limited treatment options.

The ILLUMINATE Phase 2 clinical trial ([NCT07680439](#)) is an open label, single-arm study to evaluate the efficacy and confirm the safety of BCB-276 in children and young adults with newly diagnosed DIPG following initial standard-of-care focal radiation therapy. The trial is designed as a single arm, pivotal Phase 2 registrational trial to accelerate the path to submit a biologics license application (BLA) for BCB-276 for the treatment of DIPG, based on alignment with the U.S. Food and Drug Administration (FDA). BCB-276 has also received Fast Track designation, further supporting an expedited development and regulatory review pathway. The multi-center study will be conducted at leading pediatric neuro-oncology centers throughout the United States. Site activation is complete or underway across all six selected and qualified study sites.

“Bringing this pivotal Phase 2 study forward for children battling DIPG has been our steadfast purpose at BrainChild Bio and represents the hard work of our team and the opportunity to advance our mission to combat pediatric brain cancer,” stated Michael Jensen, MD, Founder and Chief Scientific Officer of BrainChild Bio. “We aspire to bring breakthrough medicines to these children, providing hope for cures that are safe and preserve quality of life.”

As an autologous CAR T cell therapy, BCB-276 is manufactured from the participant's own immune cells, and the treatment is administered by locoregional delivery directly into the cerebrospinal fluid using an indwelling reservoir-catheter device. Patients in the study receive BCB-276 approximately every 2 weeks for a planned course of up to a total of 15 doses over approximately 7-8 months. The primary endpoint of the study is overall survival, and secondary endpoints include safety and tolerability, progression free survival, and radiographic response.

"Children and families facing a diagnosis of DIPG urgently need new treatment options. While we recognize the significant challenges in developing new therapies for DIPG, we are hopeful that our ILLUMINATE study will bring us closer to transforming the treatment landscape and delivering a meaningful therapeutic advance for these children," said Cori Abikoff, MD, Vice President of Clinical Development. "The pivotal Phase 2 ILLUMINATE study represents an important step in evaluating the potential of BCB-276 for children with newly diagnosed DIPG. We are partnering closely with leading pediatric neuro-oncology investigators and study sites to conduct this trial with the urgency and scientific rigor that this aggressive brain cancer demands."

BrainChild Bio's autologous B7-H3 CAR T cell therapy is based on a CAR T cell therapy that Dr. Michael Jensen and his team developed at Seattle Children's for the treatment of DIPG, which was exclusively licensed to BrainChild Bio. In an FDA authorized clinical study, called the BrainChild-03 Phase 1 trial ([NCT04185038](https://clinicaltrials.gov/ct2/show/study/NCT04185038)), the CAR T cell therapy exhibited a manageable safety profile in the context of outpatient administration and provided preliminary evidence of encouraging overall survival outcomes. The results of this trial were published in [Nature Medicine](#).

About Diffuse Intrinsic Pontine Glioma (DIPG) and Application of CAR T cell Therapies

Diffuse intrinsic pontine glioma (DIPG) is a primary high-grade brain tumor that arises in the pons and is uniformly fatal. DIPG affects approximately 300 children per year in the U.S. with the majority of diagnoses made in children between 5 and 10 years of age. Current standard-of-care treatment remains limited to palliative focal radiation therapy which results in a median overall survival of only about 11 months from diagnosis.¹

BrainChild Bio's autologous CAR T cell therapy offers the potential to overcome barriers to effective therapies for DIPG, including the precarious location of the tumor in the brainstem, the infiltrative growth of the tumor throughout normal brainstem functional anatomy, and the blood brain barrier that remains relatively intact during tumor progression. BrainChild Bio's CAR T cell therapies are engineered to be administered by locoregional delivery directly into the cerebrospinal fluid, permitting infused CAR T cells to directly access the tumor bed using an in-dwelling reservoir-catheter. This allows for extensive exposure of the pons to cerebrospinal fluid flow from the ventricular system, repetitive infusions of CAR T cells for more durable and sustained efficacy, and local therapeutic administration to minimize on-target, off-tumor toxicities.

About BrainChild Bio

[BrainChild Bio, Inc.](#), is a kids-first, clinical-stage biotechnology company harnessing the power of CAR T cell technology to treat tumors in the central nervous system, prioritizing pediatric indications with plans to expand into adult CNS tumors, specifically glioblastoma.

BrainChild Bio is advancing a next-generation CAR T cell therapy platform for tumors of the CNS that integrates synthetic biology technologies, including multiplex targeting to address multiple tumor antigens, novel approaches to enhance CAR T cell functionality, delivery technologies intended to support durable efficacy, and streamlined CAR T cell design and manufacturing.

BrainChild Bio's lead drug candidate is BCB-276, an autologous CAR T cell therapy that targets the immune checkpoint B7-H3, that is advancing in clinical trials for the treatment of diffuse intrinsic pontine glioma (DIPG), a pediatric cancer that forms in the brainstem which currently has limited treatment options. More information is available at www.brainchildbio.com.

¹ DIPG Registry.

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