

## Seattle Children's launches BrainChild Bio to accelerate CAR T-cell therapies for children with brain tumors

*BrainChild Bio's initial CAR T-cell therapy program will focus on advancing ongoing clinical trials evaluating safety and efficacy in pediatric brain tumors.*

SEATTLE, Wash., December 5, 2023 – Seattle Children's today announced the launch of [BrainChild Bio, Inc.](#) to accelerate the advancement of chimeric antigen receptor (CAR) T-cell therapies in Central Nervous System (CNS) tumors. BrainChild Bio will be granted an exclusive license to novel CAR T-cell technology for CNS tumors developed at Seattle Children's and will build upon the pioneering CAR T-cell therapy and clinical translational work of Michael Jensen, M.D., and his team at Seattle Children's Therapeutics. Seattle Children's has provided the initial equity funding for BrainChild Bio which will operate as an independently managed corporation.

Since 2012, Seattle Children's Therapeutics has designed, manufactured and launched a robust portfolio of immunotherapy clinical trials for leukemia and lymphoma, brain tumors, and solid tumors, enrolling more than 500 patients. The launch of BrainChild Bio is a natural progression of Seattle Children's Therapeutics' goal to expand access to potentially life-changing therapies through collaborations with biotech companies.

"As one of the largest dedicated pediatric institutes in the country, we are extremely proud of the discoveries, clinical trials and cures that have come from inside our own walls," said Dr. Jeff Sperring, Chief Executive Officer of Seattle Children's. "We also know there are kids around the globe that cannot come to Seattle to be treated. We believe this gives us the best opportunity to accelerate this technology bringing potential cures to kids faster."

BrainChild Bio's initial CAR T-cell therapy program will focus on pediatric brain tumors, prioritizing diffuse intrinsic pontine glioma (DIPG), an incurable type of childhood cancer that forms in the brainstem. The company's clinical programs will be accelerated by the foundational work at Seattle Children's Therapeutics, which consists of four clinical trials designed to validate the safety and confirm early efficacy of several different targets for CAR T-cell therapy in pediatric CNS tumors, with preliminary results planned for presentation at a scientific forum in 2024. The [BrainChild-04 clinical study](#) was initiated this year and continues to evaluate four different targets in a single CAR T-cell therapy. Following the achievement of clinical proof-of-concept in DIPG, BrainChild Bio plans to seek pediatric registration for DIPG and then extend the therapeutic application of its novel CAR T-cell therapies to target additional difficult-to-treat pediatric and adult brain tumors, including glioblastoma and brain metastases.

"As a physician, I work with children and their families who have limited therapeutic choices to treat their tumors—and it is devastating that there are few safe and curative options for them," commented Dr. Nicholas Vitanza, CNS CAR T-cell Lead and DIPG Research Lead at Seattle Children's, and the Founding Chair of BrainChild Bio's Scientific Advisory Board. "Developing therapies that are tailored specifically for pediatric patients will generate better medicines to address CNS tumors while protecting these young patients and their developing bodies and minds."

BrainChild Bio will optimize the application of CAR T-cell therapies for CNS tumors by advancing a next-generation CAR T-cell therapy platform that integrates synthetic technologies, including multiplex targeting

and enhanced potency controls. This multi-dimensional approach includes: (i) multiple targets in a single CAR T-cell therapy to prevent tumor escape; (ii) novel transgenes to increase potency that engage only when within the direct tumor environment; (iii) switching technologies to control the CAR T cells directly within the tumor; (iv) CAR T design and manufacturing processes which have been proven over many years at Seattle Children's Therapeutics, and (v) novel CAR T-cell administration directly into the brain minimizing systemic toxicities and enabling regular repeat dosing to ensure prolonged presence of CAR T-cells and durable efficacy.

"BrainChild Bio is founded with a mission to bring the best ideas forward to push the bounds of scientific discovery in service of children with cancer. For far too long, children have been deprioritized for commercialized medicines, and families have been left without options," stated Dr. Michael Jensen, Founder and Chief Scientific Officer of BrainChild Bio. "We are steadfast in our commitment to cracking the code of harnessing CAR T-cell technology in CNS tumors and we are uniquely positioned to do so."

BrainChild Bio will be led by world-class business and scientific leaders with a deep track record of innovative drug development. Steven Brugger will serve as Chief Executive Officer, bringing over 40 years of experience leading biopharma companies, most recently as CEO of Affinivax, Inc., a vaccine innovator acquired by GSK for \$3.3 billion in 2022. Dr. Michael Jensen will serve as Chief Scientific Officer, directing all research and development efforts focused on commercializing a pipeline of CNS CAR T-cell therapies. Dr. Jensen's contributions to immunotherapy are significant with over 200 patents in cell and gene therapy, spanning his 30-year career as a physician-scientist, including the last 13 years where he led the R&D team at Seattle Children's Therapeutics and developed a portfolio of CAR T-cell therapies, directed clinical translation programs and oversaw clinical studies for multiple CAR T-cell therapies. He is the scientific founder of Umoja Biopharma, as well as Juno Therapeutics, which was eventually bought by Bristol Myers Squibb and led to the commercialization of Breyanzi<sup>®</sup>, a CD19-targeting CAR T-cell therapy now commercially available for treating lymphoma in adults.

### **About Seattle Children's**

Seattle Children's mission is to provide hope, care and cures to help every child live the healthiest and most fulfilling life possible. Together, Seattle Children's Hospital, Research Institute and Foundation deliver superior patient care, identify new discoveries and treatments through pediatric research, and raise funds to create better futures for patients. Ranked as one of the top children's hospitals in the country by *U.S. News & World Report*, Seattle Children's serves as the pediatric and adolescent academic medical center for Washington, Alaska, Montana and Idaho – the largest region of any children's hospital in the country. As one of the nation's top five pediatric research centers, Seattle Children's Research Institute is internationally recognized for its work in neurosciences, immunology, cancer, infectious disease, injury prevention and much more. Additional information is available at <https://www.seattlechildrens.org/>.

### **About BrainChild Bio, Inc.**

[BrainChild Bio](#) is a kids-first, clinical-stage biotechnology company harnessing CAR T-cell technology for tumors in the central nervous system (CNS), prioritizing pediatric indications with plans to expand its technology platform to adult brain tumors. The company launched out of Seattle Children's and is led by Dr. Michael Jensen, a pioneer in the cancer immunotherapy field, and leverages over a decade of translational research conducted at Seattle Children's Therapeutics, including FDA-authorized INDs covering four CAR T-cell therapies for CNS tumors. BrainChild Bio is advancing a next-generation CAR T-cell therapy platform that weaves together synthetic technologies, including

multiplex targeting and enhanced potency controls, to provide transformational therapies for tumors of the CNS — prioritizing children, so they can grow and thrive. More information is available at <https://www.brainchildbio.com/>.

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