



IN8bio Completes Treatment of First Cohort in Phase 1 Clinical Trial with Gamma Delta T-Cell Therapy in Patients with Newly Diagnosed Glioblastoma Multiforme

Single-dose administration of IN8bio's genetically modified gamma delta T-cells in lymphodepleted glioblastoma multiforme (GBM) patients was well tolerated

No observed dose limiting toxicities (DLTs) such as infusion reactions, cytokine release syndrome (CRS), or neurotoxicity

The first treated patient survived to 15.6 months post-diagnosis compared to an expected median overall survival of 10 months given multiple poor prognostic factors

Cohort 2 of Phase 1 study with multiple repeat doses enrolling

Clinical trial update presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting ([Abstract # 2057](#))

NEW YORK, June 7, 2021 -- IN8bio, Inc. ("IN8bio" or "the Company"), a clinical-stage biopharmaceutical company focused on the discovery and development of innovative gamma delta T-cell therapies utilizing its DeltEx platform, today announced an update from the ongoing Phase 1 clinical trial of INB-200, its DeltEx drug resistant immunotherapy (DRI), MGMT-gene modified gamma delta T-cells in patients with newly diagnosed GBM. INB-200 was co-administered to patients undergoing the standard-of-care therapy for GBM during the temozolomide (TMZ) maintenance treatment.

The Phase 1 clinical trial of INB-200 ([NCT04165941](#)) is the first-in-human trial of a genetically modified gamma delta T-cell therapy. The therapy was well-tolerated with no observed infusion reactions, cytokine release syndrome (CRS), neurotoxicity or dose limiting toxicities (DLTs). The clinical program also cleared a data safety monitoring board (DSMB) review earlier in 2021 and enrollment for cohort 2 has been initiated. The trial is being conducted by Dr. Burt Nabors at the O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB). The clinical trial poster was presented at the 2021 ASCO Annual Meeting from June 4-8.

"Our DeltEx DRI platform combines the advantages of gamma delta T-cells with proprietary genetic engineering and next-generation cell therapy manufacturing that addresses the challenges of treating solid tumor cancers," said William Ho, Chief Executive Officer, and co-founder. "Given the potential safety concerns of cellular therapies for solid tumor cancers, we are encouraged by this clinical update from our INB-200 trial in GBM patients. We believe that our Phase 1 program provides early

evidence that gamma delta T-cells modified to be chemotherapy resistant are well-tolerated, with indications of clinical activity. Based on the initial safety profile, IN8bio has initiated Cohort 2 of this study, in which patients will receive three repeat doses of our DeltEx DRI product, INB-200.”

Title: Phase 1 trial of Drug Resistant Immunotherapy: A first-in-class combination of MGMT-modified $\gamma\delta$ T-cells and temozolomide chemotherapy in newly diagnosed Glioblastoma

Authors: Louis B. Nabors, Lawrence S. Lamb Jr., Melissa J. Beelen, Thriumaine Pillay, Mariska ter Haak, Samantha Youngblood, Louis Vaickus, Mina Lobbous

Track: Central Nervous System Tumors

Abstract Number: 2057

The study is an open-label Phase 1 clinical trial evaluating DeltEx DRI, gamma delta T-cells genetically modified to express proteins that confer resistance to alkylating chemotherapies, in newly diagnosed GBM patients. Gamma delta T-cells are collected from the patient, expanded, activated and genetically modified with a proprietary process developed at IN8bio. Following surgery to remove the tumor and treatment with TMZ and radiation, patients in cohort 1 received a single intracranial dose of INB-200, during their TMZ maintenance phase. The primary endpoints of this Phase I trial are based on safety and tolerability, with secondary endpoints based on biologic response, progression free and overall survival.

The results of the study to date suggest that our INB-200 treatment is well-tolerated in lymphodepleted patients. Immunologic monitoring data presented at ASCO demonstrates that peripheral circulating T, Natural Killer (NK), and gamma delta T-cells decline and are suppressed during radiation + TMZ and remain as such through maintenance TMZ therapy. An advantage of this clinical approach in newly diagnosed GBM is that TMZ, the standard-of-care therapy, serves as the lymphodepleting agent for the cellular therapy. To date, two of three patients remain alive at 10 and nine months respectively. One treated patient was infused with INB-200 in May 2020 and, despite multiple poor prognostic factors including male sex, older age, MGMT-unmethylated and IDH wild-type GBM survived for 15.6 months post-diagnosis with stable disease before expiring from causes not related to GBM progression or INB-200 infusion. Based on the results to date, the Phase 1 study has initiated enrollment of patients in the second cohort, in which each patient will receive 3 repeat doses of INB-200, a DeltEx DRI product.

About IN8bio

IN8bio is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T-cell product candidates for solid and liquid tumors. Gamma-delta T-cells are a specialized population of T-cells that possess unique properties, including the ability to differentiate between healthy and diseased tissue. These cells embody properties of both the innate and adaptive immune

systems and can intrinsically differentiate between healthy and diseased tissue. IN8bio's DeltEx platform employs allogeneic, autologous and genetically modified approaches to develop cell therapies, designed to effectively identify and eradicate tumor cells. IN8bio is currently conducting two investigator-initiated Phase 1 clinical trials for its lead gamma-delta T-cell product candidates: INB-200 for the treatment of newly diagnosed glioblastoma and INB-100 for the treatment of patients with leukemia undergoing hematopoietic stem cell transplantation. IN8bio also has a broad portfolio of preclinical programs focused on addressing other solid tumor types. For more information about IN8bio and its programs, please visit www.IN8bio.com.

About the DeltEx platform

The DeltEx platform is designed to overcome many of the challenges associated with the expansion, genetic engineering, and scalable manufacturing of gamma-delta T-cells. This approach enables the expansion of the cells, *ex vivo*, for administration of potentially therapeutic doses to patients, harnessing the unique properties of gamma-delta T-cells, including their ability to broadly recognize cellular stress signals on tumor cells. The DeltEx platform is the basis of a deep pipeline of innovative product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes.

Forward Looking Statements

Certain statements herein concerning the Company's future expectations, plans and prospects, including without limitation, the Company's current expectations regarding the advancement of its product candidates through preclinical studies and clinical trials and the prospects for such candidates and underlying technology, constitute forward-looking statements. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," the negative of these and other similar expressions are intended to identify such forward looking statements. Such statements, based as they are on the current expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond the Company's control. Consequently, actual future results may differ materially from the anticipated results expressed in such statements. Specific risks which could cause actual results to differ materially from the Company's current expectations include: scientific, regulatory and technical developments; failure to demonstrate safety, tolerability and efficacy; final and quality controlled verification of data and the related analyses; expense and uncertainty of obtaining regulatory approval, including from the U.S. Food and Drug Administration; and the Company's reliance on third parties, including licensors and clinical research organizations. Do not place undue reliance on any forward-looking statements included herein, which speak only as of the date hereof and which the Company is under no obligation to update or revise as a result of any event, circumstances or otherwise, unless required by applicable law.

Company Contact:

IN8bio, Inc.
Kate Rochlin, Ph.D.
+1 646.600.6GDT (6438)
info@IN8bio.com

Investors:

Solebury Trout

Julia Balanova

+ 1 646.378.2936

jbalanova@soleburytrout.com

Media:

Burns McClellan, Inc.

Ryo Imai / Robert Flamm, Ph.D.

+1 212.213.0006 - ext. 315 / 364

rimai@burnsmc.com / rflamm@burnsmc.com