IN8bio Announces Clinical Updates from the Phase 1 Clinical Trial of its Genetically Modified Gamma-Delta T Cell Therapy in Newly Diagnosed Glioblastoma Multiforme

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- *INB-200 is the first-ever genetically modified gamma-delta T cell therapy in clinical trials and is currently in a repeated-dose escalation cohort*
- *Cohort 1 dosing is complete with three patients who received a single dose of INB-200 with no dose limiting toxicities (DLTs), cytokine release syndrome (CRS), or neurotoxicity, and a manageable safety profile*
- *Cohort 2 is enrolling with one patient having received all three doses of INB-200, the first-ever repeat dosing of genetically modified gamma-delta T cells*
- *Of the four patients treated to date, all have exceeded their expected progression-free survival (PFS) interval, with an encouraging trend in OS*[1-3]

NEW YORK, Jan. 06, 2022 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on the discovery and development of innovative gamma-delta T cell therapies utilizing its DeltEx platform, provided an update today from the ongoing Phase 1 clinical trial of INB-200, an autologous DeltEx drug resistant immunotherapy (DRI). DeltEx DRI consists of gamma-delta T cells that have been genetically engineered to be chemotherapy resistant, allowing them to be administered concurrently with alkylating chemotherapeutic agents, including temozolomide (TMZ). This clinical trial, conducted in patients newly diagnosed with glioblastoma multiforme (GBM), is the first and most clinically advanced trial to use genetically modified gamma-delta T cells and includes a multi-dose escalation regimen.

Cohort 1 accrual and treatment is complete with three patients having received a single dose of DeltEx DRI via intracranial infusion concurrent with maintenance TMZ administration. Cohort 2 is currently recruiting and treating patients, with one patient having completed all three doses administered intracranially at 28-day intervals concurrent with maintenance TMZ. The Phase 1 clinical trial of INB-200 (NCT04165941) and the progress reported here constitute the first single- and multiple-dosed patients with genetically modified gamma-delta T cells in any indication.

INB-200 has had a manageable safety profile in all four patients treated to date, with no DLTs, CRS, immune effector cell-associated neurotoxicity syndrome (ICANS) or treatment-related serious adverse events (SAEs). The data to-date indicate promising PFS and OS, which will continue to be assessed on an on-going basis, with additional data anticipated at medical meetings later this year along with comprehensive biological correlative data.

“Patients with GBM have poor prognoses with a median survival of 14.6 to 16.6 months and PFS of approximately 4 to 6.9 months. The data reported today suggest that INB-200 may have the potential to extend both progression-free and overall survival compared with standard-of-care in the front-line setting,” said Trishna Goswami, MD, Chief Medical Officer at IN8bio. “We believe that the combination of our DRI technology and the potential to administer multiple doses of INB-200 could lead to improved efficacy results by making our gamma-delta T cells resistant to chemotherapy induced cell death, potentially permitting prolonged and more efficient tumor killing. This approach may overcome the limited efficacy observed in clinical trials of other cellular therapies in patients with solid tumors.”

“We are pleased to see that INB-200 has continued to be well-tolerated in both the single and multiple-dose treated patients to-date,” said principal investigator, L. Burt Nabors, MD at the O’Neal Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB). “GBM is one of the most difficult cancers to treat, with an urgent need for new therapies. One of the significant hurdles to the use of cellular therapies in solid tumors is the impact of chemotherapies on immune cells, which has been uniquely addressed in the engineering of the DeltEx DRI cells.”

Four patients have been treated to-date. In cohort 1, all have exceeded their expected PFS interval, with an encouraging trend in OS based on standard-of-care for their respective age and methylguanine-DNA methyltransferase (MGMT) status[1-3]. One of these patients remains alive at 17 months post-treatment, having exceeded their expected PFS and OS. As previously reported, a second patient survived for 15.6 months, with a PFS of 8.3 months, and died from an unrelated medical event without further progression. The third patient in cohort 1 exceeded predicted PFS and died at 9.6 months due to progression. In cohort 2, the first patient to complete all three doses has stable disease at 6.9 months and remains in follow-up. An earlier patient enrolled in cohort 2 completed two doses of INB-200 but died due to an acute cardio-pulmonary event without further disease progression. This was reviewed by the data safety monitoring board (DSMB) and the FDA who deemed the event unlikely to be related to therapy, and the study was allowed to continue uninterrupted. Neither patient dosed in cohort 2 experienced any infusion reactions, CRS, DLTs, or ICANS. Patient recruitment and treatment are ongoing with anticipated completion of enrollment in 2022.

INB-200 is an investigator initiated, open-label Phase 1 clinical trial evaluating IN8bio’s DeltEx DRI therapy in newly diagnosed GBM patients. Patients in cohort 1 received a single dose of INB-200, while patients in cohort 2 receive three doses at 28-day intervals and patients in cohort 3 are planned to receive six doses at 28-day intervals. All doses are given concurrently with maintenance TMZ and are intended to eliminate residual cancer during the vulnerable period of chemotherapy-induced tumor injury, when immune stress ligand expression is upregulated. The primary endpoints of this Phase 1 trial are safety and tolerability, with secondary endpoints based on biologic response, progression free and overall survival.

References

[1] NEJM 2005;352:987-996. DOI: 10.1056/NEJMoa043330

[2] NEJM 2005;352997-1003. DOI: 10.1056/NEJMoa043331
[3] NEJM 2017;376:1027-1037 DOI: 10.1056/NEJMoa1611977

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.

The proprietary IN8bio DeltEx platform is designed to overcome many of the challenges associated with the expansion, genetic engineering, and scalable manufacturing of gamma-delta T cells. The DeltEx platform employs allogeneic, autologous, and genetically modified approaches to develop cell therapies, designed to effectively identify and eradicate tumor cells. This approach allows us to expand the cells *ex vivo* to administer a potentially therapeutic dose to patients, harnessing the unique properties of gamma-delta T cells, including their ability to broadly recognize cellular stress signals on tumor cells. We have used the DeltEx platform to create our deep pipeline of innovative allogeneic, autologous and/or genetically modified product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes.

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.

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, including the ability of INB-200 to treat GBM, constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995. 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, technical and clinical 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; the impact of the ongoing COVID-19 pandemic on the Company's clinical trials; 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.

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