IN8bio Announces Positive INB-200 Phase 1 Data Update in Glioblastoma at the 2023 ASCO Annual Meeting

June 5, 2023

- *100% of treated patients (n=8) to date have exceeded historical median progression-free survival, with two patients that received three doses remaining progression-free at 23.5 and 19.4 months, respectively.*
- *INB-200 continues to exhibit a manageable safety profile with minimal toxicities and repeat dosing demonstrated no change in the toxicity profile.*
- *Company is on track to complete INB-200 Phase 1 study enrollment in 2023 with updated data expected later this year.*

NEW YORK, June 05, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company focused on innovative gamma-delta T cell therapies, announced updated data from the ongoing Phase 1 clinical trial of INB-200 in patients with newly diagnosed glioblastoma multiforme (GBM). The data were featured as one-of-four oral presentations and the only Phase 1 study during the immunotherapy section of the Central Nervous System Tumors session at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting in Chicago, Illinois.

“The standard-of-care for GBM over the past twenty years falls short, with a median progression-free survival of just 4 to 7 months and overall survival of only 14 to 16 months. We are thrilled to see that two patients who have received three doses of INB-200 remain progression-free, clinically asymptomatic and off treatment for a prolonged period of time,” said Trishna Goswami, M.D., Chief Medical Officer of IN8bio. “Further, the use of multiple doses in later cohorts have not led to a change in the toxicity profile, which may enable patients to stay on treatment longer and, ultimately, improve outcomes.”

The oral presentation at ASCO includes efficacy and safety data as of a data cutoff of April 30, 2023. Eight patients have been treated with INB-200: three in Cohort 1 (single dose), four in Cohort 2 (three doses) and one in Cohort 3 (six doses). As of May 19, 2023 key findings from the ongoing study include:

- Cohort 1 patients remained progression-free at 8.3, 11.9, and 7.4 months, with respective overall survival (OS) of 15.6, 17.7, and 9.6 months.
- Two patients in Cohort 2 remain alive and progression-free at 23.5 and 19.4 months, respectively, exceeding median OS of GBM patients without progression.
- In Cohort 3, the first patient dosed received five of six planned doses of gamma-delta T cells and had a progression-free survival (PFS) of 7.1 months and OS of 11.8 months with no evidence of additional toxicities. This patient who had an LZRT1 mutation experienced a rare leptomeningeal relapse, along with widespread relapse in their liver, lungs and pelvis. However, there was no progression in their brain, where INB-200 was administered.
- No treatment-related deaths have been reported in any cohort. Six deaths were observed, three due to progression of disease and three unrelated to either treatment or progression (the deaths were due to sepsis, a cardiac event and pulmonary embolism).
- No treatment-related serious adverse events (SAEs), dose-limiting toxicities (DLTs) cytokine release syndrome (CRS), infusion reactions, or immune effector cell-associated neurotoxicity syndrome (ICANS) have been reported in any cohort.
- The most common treatment emergent adverse events (TEAEs) were white blood cell and platelet count decreases related to standard-of-care temozolomide, asthenia, headache and hydrocephalus, mostly Grade 1-2.
- Three additional patients have been consented in Cohort 3 to date and are advancing through treatment.

“INB-200 has proven to be a safe and feasible method of delivering an innovative cell-based immunotherapy for newly diagnosed glioblastoma patients,” said Dr. Burt Nabors, director of the Division of Neuro-Oncology in the University of Alabama at Birmingham Marnix E. Heersink School of Medicine.

The Company expects to provide further clinical updates later this year as study enrollment continues. The ASCO presentation titled "**INB-200 Phase I Study of Gene Modified Autologous Gamma-Delta (γδ) T Cells in Patients with Newly Diagnosed Glioblastoma Multiforme (GBM) Receiving Maintenance Temozolomide (TMZ)**" (Abstract #2007) can be found at https://investors.in8bio.com.

About INB-200

INB-200 is a genetically modified autologous drug resistant immunotherapy (DRI) product candidate for the treatment of solid tumors. This novel platform utilizes genetic engineering to generate chemotherapy resistant gamma delta T cells which can be administered concurrently with standard-of-care treatment in solid tumors. This is a powerful, synergistic treatment approach is intended to enable gamma-delta T cells to persist in the presence of chemotherapy, and maintain their natural ability to recognize, engage and kill cancer cells.

INB-200 is the first genetically engineered gamma-delta T cell therapy to be administered to patients with solid tumors and our initial indication is in GBM.

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. IN8bio's DeltEx platform employs allogeneic, autologous, iPSC 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 is initiating INB-400, a company-sponsored Phase 2 clinical trial in newly diagnosed glioblastoma following IND clearance in late 2022. IN8bio also has a broad portfolio of preclinical programs focused on addressing hematological and other solid tumor types. For more information about IN8bio and its programs, please visit www.IN8bio.com.

Forward Looking Statements

This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding the timing of initiation, progress and scope of clinical trials for IN8bio's product candidates, including INB-100, INB-200 and INB-400; and IN8bio's ability to achieve anticipated milestones, including expected data readouts from its trials, enrollment of additional patients in its clinical trials, and advancement of clinical development plans. IN8bio may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as IN8bio's ability to meet anticipated deadlines and milestones, presented by public health crises as well as rising inflation and regulatory developments; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of IN8bio's product candidates; the risk that IN8bio may not realize the intended benefits of its DeltEx platform; availability and timing of results from preclinical studies and clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of IN8bio's product candidates; expectations for regulatory approvals to conduct trials or to market products; IN8bio's reliance on third parties, including licensors and clinical research organizations; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, which are described in greater detail in the section entitled "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 12, 2023, as well as in other filings IN8bio may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and IN8bio expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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