IN8bio Announces Positive Glioblastoma Multiforme (GBM) Clinical Updates from the INB-200 Phase 1 Trial Presented at ASCO 2022

June 6, 2022

- *100% of dosed patients have exceeded both median and expected progression free survival (PFS). Two patients, to date, having exceeded their expected overall survival (OS).*
- *An unmethylated GBM patient remains stable at one-year post enrollment. Patient received three-repeated doses and is without disease progression, has doubled expected PFS and remains off steroids.*
- *All patients dosed demonstrating a manageable safety and tolerability profile.*
- *The first two cohorts are fully enrolled and enrollment has initiated for cohort 3, with additional clinical updates expected later in 2022.*

NEW YORK, June 06, 2022 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on the discovery and development of gamma-delta T cell therapies, today announced updated safety and durability data from the Phase 1 clinical trial of INB-200 in patients with newly diagnosed glioblastoma multiforme (GBM). The data were presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. INB-200 is a genetically engineered gamma-delta T cell product candidate that is designed to be chemotherapy resistant as part of the company's core Drug Resistant Immunotherapy (DRI) platform.

"INB-200 continues to show promising activity in this challenging disease," said Trishna Goswami, M.D., Chief Medical Officer of IN8bio. "All patients have exceeded their expected PFS and some have exceeded expected OS even with poor prognostic factors such as MGMT unmethylated disease. We are particularly encouraged by patients in the repeated dose cohort that continue to do well, including one patient that has recently reached the 1-year progression-free milestone, demonstrating durable stable disease and having returned to work."

IN8bio is a leader in gamma-delta T cells and INB-200 was the first genetically modified gamma-delta T cell therapy to enter clinical trials. The Phase 1 trial of INB-200 completed enrollment of the first two cohorts with INB-200 being well tolerated with no dose limiting toxicities, cytokine release syndrome or neurotoxicity to date. O^6-methylguanine DNA methyltransferase (MGMT) is a prognostic biomarker used in glioblastoma whereby unmethylated tumors are unresponsive to treatment with chemotherapeutic agents such as temozolomide (TMZ). INB-200 has shown early, but encouraging, observations of prolonged PFS in patients with both MGMT unmethylated and methylated GBM. Positive immune responses in these patients have been supported by the company's previously reported data demonstrating increased peripheral immune cells following treatment. Additionally, histopathologic observations of dead necrotic tissue and elevated intratumoral gamma-delta T cells have been obtained from re-resection tissue from an unmethylated GBM patient approximately 150 days following treatment with INB-200. This trial is an investigator initiated open-label study being conducted by Dr. Burt Nabors at the O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB) Marnix E. Heersink School of Medicine in collaboration with IN8bio. UAB and IN8bio presented the updated clinical data during a poster presentation at the ASCO Annual Meeting in Chicago on June 5, 2022.

Presentation details:

Title:	**Phase I Study of Drug Resistant Immunotherapy (DRI) with Gene Modified Autologous γδ T Cells in Newly Diagnosed Glioblastoma Multiforme (GBM) Patients Receiving Maintenance Temozolomide (TMZ)**
Abstract:	2044
Poster:	382

As of June 3, 2022, six patients have been dosed with INB-200, three in Cohort 1 (single dose) and three in Cohort 2 (three doses) with the one additional patient in cohort 2 still awaiting treatment. There have been no treatment related serious adverse events (SAEs) or dose limiting toxicities (DLTs) observed to date. There have been no cytokine release syndrome (CRS), infusion reactions, or immune effector cell-associated neurotoxicity syndrome (ICANS). Adverse events have generally been tolerable and include grade 1/2 anemia, fevers, headaches, myelosuppression and nausea. Importantly, to date, repeat dosing does not demonstrate a change in toxicity profile. Patients in cohort 1 and 2 each received 1 x 10^7 DRI gamma-delta T cells intratumorally on Day 1 of a 28-day treatment cycle for a total of 1 and 3 cycles respectively, along with standard of care TMZ. The primary endpoint of this trial is safety; secondary endpoints include progression free and overall survival.

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 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

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 potential of IN8bio’s INB-200 program; the progress and scope of clinical trials for IN8bio’s product candidates; and IN8bio’s ability to achieve planned milestones, including data readouts from its clinical trials. 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 the ongoing COVID-19 pandemic; uncertainties inherent in the conduct and completion of 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 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, are described in greater detail in the section entitled “Risk Factors” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 17, 2022, 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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