IN8bio Provides INB-200 Clinical Update and Outlines 2023 Pipeline Goals

January 5, 2023

- *All three patients exceeded the median progression-free survival (PFS) of seven months with two ongoing responses extending beyond 1.5 years and 1.2 years progression-free, respectively, in initial data from Cohort 2 of the Phase 1 INB-200 trial in newly diagnosed glioblastoma multiforme (GBM).*
- *Company-sponsored Phase 2 multi-center clinical trial of autologous INB-400 gamma-delta T cells in newly diagnosed GBM patients to start enrollment by Q3 2023.*
- *Submission of Investigational New Drug Application (IND) for the Phase 1b trial of INB-410, a genetically modified allogeneic gamma-delta T cell therapy in relapsed and newly diagnosed GBM anticipated in 2H 2023.*
- *Announcement of a new solid tumor indication with relevant data at a scientific conference in 1H 2023.*

NEW YORK, Jan. 05, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced a clinical update from the ongoing Phase 1 trial evaluating INB-200 in patients with newly diagnosed GBM and provided pipeline goals for 2023.

Clinical Update from the INB-200 Phase 1 Trial

- As of December 31, 2022, eight patients have been dosed with INB-200: three in Cohort 1 (single dose), four in Cohort 2 (three doses) and one in Cohort 3 (six doses). Enrollment is ongoing, with clinical updates expected throughout 2023. Key findings from the ongoing study include:
  - All patients in Cohort 2 remained progression free at 18.9, 14.8, and 8.7 months, respectively. The third patient died at 8.7 months due to a pulmonary embolism unrelated to treatment with no evidence of relapse prior to death.
  - Two patients continue to exceed the median survival for GBM patients with the standard Stupp regimen, suggesting that increasing doses of gamma-delta T cells may favor longer PFS and overall survival (OS).
  - The first patient dosed in Cohort 3 has received five doses of gamma-delta T cells with no evidence of additional toxicities. The patient has no local GBM relapse, which is typical in 95% of GBM cases, but does have evidence of distal leptomeningeal disease.
  - There have been no treatment-related serious adverse events (SAEs) or dose-limiting toxicities (DLTs) observed to date. There have been no instances of cytokine release syndrome (CRS), infusion reactions, or immune effector cell-associated neurotoxicity syndrome (ICANS).
  - Adverse events have been generally tolerable and include grade 1/2 anemia, fevers, headaches, myelosuppression, and nausea. Importantly, to date, repeat dosing does not demonstrate a change in the toxicity profile.

“We believe that 2023 will be a pivotal year for IN8bio as we advance our innovative chemotherapy-resistant cell therapy to improve outcomes for patients living with cancer,” said William Ho, Chief Executive Officer of IN8bio. “We are encouraged to see greater durability of response with increased dosing of our cells, along with a continued favorable safety profile in this Phase 1 study of INB-200. We look forward to multiple milestones across our pipeline in the year ahead, including initiating our Phase 2 study of INB-400 in newly diagnosed GBM and advancing additional solid tumor indications outside of GBM.”

Anticipated 2023 Pipeline Goals

- **INB-100:** Report Phase 1 ongoing trial data from leukemia patients undergoing haploidentical stem cell transplantation (HSCT); define maximum tolerated dose for INB-100.
- **INB-200 in GBM:** Complete enrollment of Cohort 3 in the Phase 1 trial; report additional data and topline results with longer-term follow-up.
- **INB-300:** Present preclinical data demonstrating proof-of-concept of non-signaling CAR (ns-CAR) platform in 1H 2023.
- **INB-400:** Initiate patient enrollment in the company-sponsored Phase 2 trial of INB-400, a genetically modified autologous gamma-delta T cell therapy, targeting newly diagnosed GBM by Q3 2023.
- **INB-410:** Submit IND to the FDA for a Phase 1b trial of INB-410, a genetically modified allogeneic gamma-delta T cell therapy in newly diagnosed and relapsed GBM.

- **New solid tumor indications:** Announce and present relevant data at a scientific conference in 1H 2023.

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 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; the potential of INB-100 to treat and increase the cure rates in patients with high-risk or relapsed acute myeloid leukemia (AML) and other hematologic malignancies; and IN8bio's ability to achieve anticipated milestones, including expected data readouts from its trials, enrollment of additional patients in its clinical trials, announcement of a new solid tumor indication and advancement of clinical development plans, including plans to file an IND application for INB-410. 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 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, 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 November 10, 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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