IN8bio Presents Positive, New INB-100 Data Showing Long-term Complete Remissions and Elevated Gamma-Delta T Cells in 100% of Evaluable Treated Leukemia Patients at EBMT 2023

April 24, 2023

- *INB-100 treatment has achieved durable 100% complete remission (CR) in treated patients, including high-risk acute myeloid leukemia (AML) patients and a patient with acute lymphoblastic leukemia (ALL) who had failed 4 prior lines of therapy, including CAR-T, with all evaluable patients remaining alive at last assessment and one patient out beyond 3 years.*
- *The latest data shows that allogeneic gamma-delta T cell expansion and persistence continued up to 180 days post-treatment, marking the first-ever demonstration of this type of response in an allogeneic cellular therapy.*
- *With its generally favorable safety profile and evidence of gamma-delta T cell expansion, Dose Level 2 has been selected as the recommended Phase 2 dose (RP2D) for further cohort expansion.*
- *The company will be holding a conference call at 10:00 a.m. ET today to discuss the latest clinical updates and data.*

NEW YORK, April 24, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced new positive data from the Phase 1 investigator-sponsored trial of INB-100 in leukemia patients. The data presented at the 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) showed that 100% of evaluable patients (n=7) treated with INB-100 remained alive, progression-free, and in durable complete remission (CR) as of April 21, 2023, indicating the curative potential of INB-100 for high-risk or relapsed AML and other hematologic malignancies undergoing hematopoietic stem cell transplantation (HSCT).

“We are thrilled to report that 100% of evaluable dosed patients remain in morphological CR with the first three high-risk AML patients with complex cytogenetics now alive and relapse-free, with one patient surviving for as long as 3 years,” said Dr. Trishna Goswami, IN8bio's Chief Medical Officer. Further, “INB-100 has demonstrated, for the first time, in vivo expansion and persistence of an allogeneic, or donor-derived cellular therapy at the higher levels associated with greater survival outcomes.”

The latest data on immune reconstitution presented at EBMT showed significant allogeneic gamma-delta T cell expansion and persistence in patients through the first 180 days post-treatment. Patients who received INB-100 treatment at Dose Level 2 exhibited an average of 82.9x greater gamma-delta T cell expansion at 60 days compared to patients undergoing haploidentical HSCT without INB-100 therapy. The gamma-delta T cell levels in Dose Level 2 patients are also, on average, 12.8x greater than those achieved in Dose Level 1, demonstrating a dose-response related to the gamma-delta T cell infusion. Elevations in CD4+, CD8+ T cells, NK cells and B cells have also been observed, indicating a broad positive immune response.

The study's updated safety data reported low-grade (1-2) graft versus host disease (GvHD) in all patients treated, which was steroid-responsive, and had a more rapid onset at higher dose levels. No dose limiting toxicities (DLTs) have been observed. As of April 21, 2023, all evaluable patients across Dose Levels 1 and 2 remained on study and in CR, with one patient remaining progression free for over 3 years. Additional treated patients have remained progression free for 33.9, 22.2, 7.8, 5.8, 5.6 and 2.6 months, respectively.

“The data that continue to emerge from this clinical trial are very encouraging and suggest that INB-100 may offer a new treatment option for this high-risk population,” said Dr. Joseph McGuirk, the Schutte-Speas Professor of Hematology-Oncology, Division Director of Hematological Malignancies and Cellular Therapeutics and Medical Director, Blood and Marrow Transplant at The University of Kansas Cancer Center and the Principal Investigator on the study. “While the data are early, it is encouraging that all evaluable treated patients have shown positive clinical outcomes and durable responses, particularly in light of the high-risk and complex cytogenetics of these patients.”

The positive outcome of ongoing durable patient CRs, combined with the benefit/risk profile, led to the decision to select Dose Level 2 as the RP2D. The trial is being expanded at this dose level, and additional patients are actively being enrolled and treated in the study, with updated data expected to be presented at a medical meeting later this year.

Conference Call Details
IN8bio will host a conference call and webcast today, April 24, 2023, at 10:00 a.m. ET to review the updated data from the EBMT presentation, as well as recent clinical updates. The webcast can be accessed by clicking the link: https://edge.media-server.com/mmc/p/kr56s22f and can also be accessed on the Events & Presentations page of the Company’s website.

About the INB-100 Phase 1 Trial
The Phase 1 clinical trial (NCT03533816) is an investigator-sponsored dose-escalation trial of allogeneic derived, gamma-delta T cells from matched related donors that have been expanded and activated *ex vivo* and administered systemically to patients with leukemia following HSCT. The single-institution clinical trial is currently being conducted at The University of Kansas Cancer Center (KUCC). The primary endpoints of this trial are safety and tolerability, and secondary endpoints include rates of GvHD, relapse rate 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 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 ability of INB-100 to treat and increase the cure rates in patients with high-risk or relapsed 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. 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, 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 30, 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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