IN8bio Presents Positive Data Demonstrating Durable 1-year Complete Remission in 100% of Evaluable Patients in Phase 1 Trial of INB-100

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- *100% of treated leukemia patients (n=10/10) achieved durable complete remission (CR) at 1-year, including high-risk and relapsed acute myeloid leukemia (AML) patients who had previously failed multiple lines of therapy, including CAR-T.*
- *Data continue to show long-term in vivo expansion and persistence of allogeneic gamma-delta T cells 365 days following a single administration, demonstrating first-ever durable persistence and expansion of an allogeneic cellular therapy.*
- *The Company will host a conference call at 4:15 pm ET. Use this link to participate. A listen-only version of the webcast is available here.*

NEW YORK, June 13, 2024 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, presents updated data from its Phase 1 trial of INB-100 at the European Hematology Association (EHA) 2024 Hybrid Congress.

The data from INB-100 demonstrated that 100% of evaluable leukemia patients (n=10) remained alive, progression-free, and in durable CR through one year as of May 31, 2024. Historically, published data demonstrated that up to ~50% of patients with hematologic malignancies undergoing HSCT with reduced intensity conditioning (RIC) relapse by one year and often succumb to the disease shortly thereafter. Two of the patients treated with INB-100 remain alive and relapse free for over three and a half years, and a third patient is now nearing three years. Furthermore, INB-100 has demonstrated for the first time, the *in vivo* expansion and persistence of a haplo-matched allogeneic, or donor-derived, cellular therapy at 365 days, with blood levels of gamma-delta T cells surpassing levels previously associated with greater survival.

The complete responses to date, combined with a favorable safety and risk profile demonstrating no dose limiting toxicities (DLTs), no cytokine release syndrome (CRS), no neurotoxicity or immune effector cell-associated neurotoxicity syndrome (ICANS) and a lack of serious infections is encouraging for the treatment of hematological malignancies. One patient died of idiopathic pulmonary fibrosis, a known toxicity of transplants, without evidence of progression. Additionally, two patients with TP53 mutations, including one patient with Ph-acute lymphocytic leukemia (ALL) treated with seven prior treatment regimens and a patient with MDS/MPN syndrome, relapsed but remain alive. Leukemic relapse is the leading cause of death in patients undergoing HSCT, making relapse prevention a critical unmet need.

The trial has been expanded to enroll an additional ten patients at Dose Level 2 (DL2), the recommended Phase 2 dose. Enrollment and treatment of patients into the expansion cohort is ongoing, with updated data expected in late 2024 and 2025. IN8bio expects to discuss plans for a potential registrational trial for this indication with the U.S. Food and Drug Administration (FDA) in a Type B meeting this summer.

“These data demonstrate the potential of allogeneic INB-100 gamma-delta T cells to provide durable relapse-free periods for patients with high-risk or relapsed AML and other hematologic malignancies undergoing HSCT,” said Trishna Goswami, MD, Chief Medical Officer of IN8bio. “100% of evaluable patients remain in complete remission at one year of follow-up. In this trial, the first three patients were high-risk or relapsed AML patients with complex cytogenetics, including trisomy of chromosome 8 and deletion of chromosome 7. All three patients are alive and progression free with one lost-to-follow-up at 42.4 months after they relocated away from the study site and out of state. Achieving these outcomes despite giving patients a RIC regimen, which carries a higher risk of relapse, in an older population with a median age of 68 is very encouraging. We look forward to advancing our novel gamma-delta T cell therapy for patients who need additional options.”

“The emerging safety, efficacy and durability profile of this novel gamma-delta T cell therapy supports its potential to improve relapse free survival for patients with blood cancers following allogeneic stem cell transplantation,” said Dr. Joseph P. McGuirk, Schutte-Speas Professor of Hematology-Oncology, Division Director, Hematologic Malignancies and Cellular Therapeutics, and Medical Director, Blood and Marrow Transplant, at The University of Kansas Cancer Center. “Approximately 25% of patients relapse within the first 100 days, and nearly half by one year post stem cell transplant, which remains the primary cause of treatment failure and mortality. The results of this clinical trial are very encouraging and hold promise that a novel cellular therapy using donor-derived gamma-delta T cells may prevent relapse, resulting in improved relapse-free survival for patients with hematologic malignancies.”

Conference Call Details
IN8bio will host a conference call and webcast today, Thursday, June 13, 2024, at 4:15 pm ET to review the updated clinical data from the EHA presentation. The webcast can be accessed by clicking this link and can also be accessed on the Events & Presentations page of the Company’s website. To participate in the live call, please register using this link. It is recommended that participants register at least 15 minutes in advance of the call. Once registered, participants will be informed of the dial-in number and will be provided a unique PIN.

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 approximately 15 to 30 days post engraftment. The single-institution clinical trial is being conducted at The University of Kansas Cancer Center (KUCC). The primary endpoints of this trial include 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 has initiated a Phase 2 trial of INB-400 in GBM at multiple centers across the United States and has two ongoing Phase 1 trials in solid and hematological tumors, including INB-200 for GBM and INB-100 for patients with hematologic malignancies undergoing transplantation. IN8bio also has a broad portfolio of preclinical programs focused on addressing other hematological and solid tumor cancers. 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 allogeneic INB-100 gamma-delta T cells to provide durable relapse-free periods for patients with high-risk or relapsed AML and other hematologic malignancies undergoing HSCT; the ability of IN8bio to continue advancing its novel gamma-delta T cell therapy; the potential of INB-100 to improve the relapse free survival for patients with blood cancers undergoing stem cell transplantation; the potential activity and safety data of INB-100; IN8bio's plans regarding interactions with regulatory agencies, including the FDA; 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: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of IN8bio's product candidates, including patient enrollment and follow-up and IN8bio's ability to meet anticipated deadlines and milestones; 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; uncertainties related to 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 actual results to differ from those contained in the forward-looking statements, that 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 9, 2024, 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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