IN8bio Announces Positive Clinical Update Demonstrating Continued Durable Complete Remission in 100% of Evaluable Patients in Phase 1 Trial of INB-100 in Leukemia

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- *Durable complete remission (CR) achieved in 100% of treated patients, including high-risk and relapsed acute myeloid leukemia (AML) patients and those who had failed multiple prior lines of therapy, including CAR-T.*
- *All trial participants remain alive and relapse free as of last assessment, and six patients have been relapse free for over one year.*
- *New data shows long-term in-vivo expansion and persistence of allogeneic gamma-delta T cells 365 days following a single administration of INB-100, demonstrating the first-ever durable persistence of an allogeneic cellular therapy.*
- *Data to be presented today (abstract: 4853) at the 65th American Society of Hematology (ASH) Annual Meeting & Exposition.*
- *The Company will host a conference call at 8:30 am ET tomorrow to discuss these updates. Please use this link to participate in the live call; a listen-only version of the webcast is available here.*

NEW YORK, Dec. 11, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced positive updated data from its Phase 1 investigator-sponsored trial of INB-100 in patients with hematologic malignancies. The data, which will be presented in a poster presentation at the 65th ASH Annual Meeting & Exposition this evening, demonstrated that 100% of evaluable leukemia patients (n=10) treated remained alive, progression-free, and in durable complete remission (CR) as of November 3, 2023. The Company believes this data indicate the curative potential of INB-100 to provide durable relapse free periods for high-risk or relapsed AML and other hematologic malignancies undergoing hematopoietic stem cell transplantation (HSCT). The CRs to date, combined with INB-100's benefit/risk profile are encouraging for the treatment of hematological malignancies and the trial is being expanded by ten patients at Dose Level (DL) 2, the recommended Phase 2 dose (RP2D). Additional expansion patient enrollment is on-going and updated data is expected to be presented at medical meetings in 2024.

"With more patients and a longer observation period, we are excited to report that 100% of evaluable dosed patients continue to remain in morphological complete remission, with six patients remaining alive and relapse free beyond one year," said Trishna Goswami, MD, Chief Medical Officer at IN8bio. "Leukemic relapse is the leading cause of death in patients undergoing HSCT and prevention of relapse remains a high unmet need. In this trial, the first three patients were high-risk or relapsed AML patients with complex cytogenetics. We are happy to report two of the patients remain alive and relapse free for over three years, and the third is now past two years. Furthermore, INB-100 has demonstrated for the first time, the in-vivo expansion and persistence of an allogeneic, or donor-derived, cellular therapy at 365 days with blood levels of gamma-delta T cells surpassing levels previously observed to be associated with greater survival."

"Our team is excited by the potential safety, efficacy and durability of this novel cellular therapy and the possibility to improve the likelihood of cure for patients with blood cancers undergoing stem cell transplantation," 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. "Relapse post stem cell transplant remains the primary cause of treatment failure and mortality. The results of this clinical trial are very encouraging and hold great 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."

Summary of Data Presented at ASH

The latest INB-100 trial data on immune reconstitution showed significant allogeneic gamma-delta T cell expansion and persistence in patients through the first 365 days post-treatment.

Patients who received INB-100 treatment at DL 2 exhibited gamma-delta T cell levels:

- An average of 48.9x greater at 60 days compared with patients undergoing haploidentical HSCT without INB-100 therapy.
- An average of 7.6x greater than those achieved in DL 1, which continues to demonstrate a dose-response related to the gamma-delta T cell infusion.
- An average of 2.7x greater at 365 days than levels found in DL 1, which is above levels previously associated with improved survival outcomes.

Other observations:

- Elevations in CD4+, CD8+ T cells, NK cells and B cells have also been observed, indicating a broad positive immune response and stable reconstitution of the immune system post-transplant.

- New cytokine data following gamma-delta T cell infusion demonstrate peripheral increases in pro-inflammatory cytokines in the plasma, such as interferon-gamma, IL-6 and IL-15 early post-infusion, demonstrating broad immune activation.

Updated safety data includes three additional patients since in April 2023 *(as of November 3, 2023)*:

- Low grade (1-2) acute graft versus host disease (GvHD) observed in 60% of patients treated. Cases were all steroid responsive.
- No dose limiting toxicities (DLTs) have been observed.
- All evaluable patients across DL 1 and DL 2 remained on study and in CR, with two patients now remaining progression free for over 3 years.
- Treated patients have remained progression free for 42.7, 40.3, 28.6, 14.3, 12.2, 12.0, 9.0, 5.6, 5.3 and 4.9 months, respectively.

Conference Call Details
IN8bio will host a conference call and webcast tomorrow, Tuesday, December 12, 2023, at 8:30 am ET to review the updated clinical data from the ASH 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. 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 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 ability of INB-100 to continue to prevent relapse in evaluable patients; the continued ability of INB-100 to help patients remain alive, progression-free, and in durable CR; the potential of INB-100 to provide durable, relapse free periods for high-risk or relapsed AML and other hematologic malignancies undergoing HSCT; the timing of initiation, progress and scope of clinical trials for IN8bio's product candidates, including INB-100; 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, 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 9, 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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