IN8bio Reports Updated Positive Results from Phase 1 Trial of INB-100 in Leukemia Patients

February 11, 2025

- *100% of acute myeloid leukemia (AML) patients across both original and expansion cohorts remain in complete remission (CR), with a median follow-up of 20.1 months*
- *AML patients treated demonstrated one-year progression-free survival (PFS) and overall survival (OS), exceeding real-world control groups*
- *Patients treated with INB-100 demonstrating prolonged and durable remissions supported by gamma-delta T cell persistence beyond one year*
- *Company to host conference call at 8:30am EST today. Use this link to participate or access the listen-only version of the webcast here*

NEW YORK, Feb. 11, 2025 (GLOBE NEWSWIRE) -- **IN8bio, Inc. (Nasdaq: INAB)**, a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced encouraging new clinical data from the ongoing Phase 1 investigator-sponsored trial of INB-100, an allogeneic gamma-delta T cell therapy designed to help patients with complex leukemias, including AML. INB-100, given following hematopoietic stem cell transplantation (HSCT), is demonstrating the potential to achieve durable long-term remissions and improved survival. The data will be presented at the 2025 Tandem Meetings | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, hosted in Honolulu, HI.

Highlights

- **100% of AML patients remain relapse-free**
  - All treated AML patients in both the original and expansion cohorts through January 17, 2025 remain in complete remission. The original cohort of AML patients has reached a median CR of 23.3 months, with several patients in remission for over three years. The median duration across all treated AML patients (N=9) is 20.1 months.
- **Trial displays improved survival outcomes vs. standard treatment**
  When compared with real-world historical data, INB-100 demonstrated significantly higher survival rates:
  - INB-100:
    - All patients - 90.9% PFS and OS of 100% at one-year; and
    - AML patients - 100% PFS and OS of 100% at one-year.
  - Historical controls in AML:
    - Center for International Blood and Marrow Transplant Research (CIBMTR) demonstrate a PFS of 67.8% and OS of 74.7% at one-year; and
    - Kansas University Cancer Center (KUCC) PFS of 57.4% and OS of 66.7% at one-year.
- **Results demonstrate activity even with older, high-risk patients receiving reduced intensity conditioning (RIC)**
  - Relapse is the most significant challenge leading to mortality for patients undergoing HSCT.
  - Many of the patients enrolled in the study were older (median age = 68), had complex, high-risk disease or had failed multiple prior therapies, including CAR-T treatments, yet they achieved durable, long-term remission with manageable side effects.
- **Therapy appears to be well-tolerated without significantly impacting patient Quality of Life**
  - No cytokine release syndrome (CRS) or neurotoxicity; (ICANs)
  - Tolerable graft-versus-host disease (GvHD) in-line with historical data that is managed with steroids; and
  - Limited, mild infections.

Dr. Joseph P. McGuirk, Schutte-Speas Professor of Hematology-Oncology, Division Director, Hematologic Malignancies and Cellular Therapeutics Medical Director, Blood and Marrow Transplant, The University of Kansas Cancer Center, commented, “These data suggest that the addition of allogeneic INB-100 gamma-delta T cells appears to have the potential to support durable relapse-free remissions in high-risk leukemia patients, with 100% of treated AML patients remaining in remission after a median follow-up of almost two years post-transplant. Typically, patients receiving reduced-intensity conditioning face substantial risks of relapse within a year, and those who relapse are often left with very few treatment options. INB-100 is not only helping patients avoid this common relapse timeline but is doing so while helping to preserve their quality of life. These results are truly exciting. We are seeing something we rarely encounter in high-risk leukemia patients: sustained, durable remissions with minimal side effects to date. These continued results of INB-100, with the manageable toxicity profile, suggest it could become an attractive cellular therapy with the potential to extend survival in this difficult-to-treat patient population.”

William Ho, Chief Executive Officer and co-founder of IN8bio, added, "We're incredibly pleased with our efforts to continue to deliver consistent, long-term remission results with INB-100. It's rare to see 100% relapse-free survival in high-risk AML patients, especially over a prolonged period. For patients who may not have had a clear path forward in the past, INB-100 is providing hope, extending survival, and demonstrating the potential to change the standard-of-care. What makes this even more exciting is the safety profile we've observed. Gamma-delta T cells are showing that they can do the job of fighting residual cancer cells without causing significant side effects like CRS or neurotoxicity—issues that often plague other cell therapies. As we continue to enroll patients and expand the trial network, we are working diligently to lay the groundwork for the future regulatory pathway towards a potential registrational trial. The IN8bio team is working hard to de-risk the future path to approval and to bring this innovative therapy towards broader patient access. We are committed to providing further updates later this year as we build momentum toward this goal."

Conference Call Details

IN8bio will host a conference call and webcast today, Tuesday, February 11, 2025, at 8:30 am ET. 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 5 minutes in advance of the call. Once registered, participants will be informed of the dial-in number and will be provided a unique PIN.

For more information about the study – including detailed findings, conclusions and next steps – please visit the Company's poster being presented at the American Society of Transplantation and Cellular Therapy conference: https://investors.in8bio.com/news-events/events-presentations.

About IN8bio
IN8bio is a clinical-stage biopharmaceutical company developing gamma-delta T cell-based immunotherapies for cancer patients. 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. The company's lead program, INB-100, is focused on AML evaluating haplo-matched allogeneic gamma-delta T cells given to patients following a hematopoietic stem cell transplant. The company is also evaluating autologous DeltEx DRI gamma-delta T cells, in combination with standard of care, for glioblastoma. For more information about IN8bio, 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: IN8bio's ability to deliver on the potential of INB-100; the potential of allogeneic INB-100 gamma-delta T cells to provide durable long-term, relapse-free remissions in high-risk or relapsed AML patients undergoing HSCT; the ability of INB-100 to help preserve the quality of life of AML patients and to become an attractive cellular therapy with the potential to extend survival in this difficult-to-treat patient population; IN8bio's ability to achieve anticipated milestones, including expected presentations and data readouts from its trials, enrollment of additional patients in its clinical trials, and advancement of clinical development plans; IN8bio's ability to de-risk INB-100's path toward a potential registrational trial and achieve future approval and broader patient access; and other statements that are not historical fact. 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; 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 be unable to raise additional capital and could be forced to delay, further reduce or to explore other strategic options for certain of our development programs, or even terminate its operations; IN8bio's ability to continue to operate as a going concern; 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; the uncertainty of 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 12, 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.

Investors & Company Contacts:
Glenn Schulman, PharmD, MPH
203.494.7411
gdschulman@in8bio.com

IN8bio, Inc.
Patrick McCall
646.933.5603
pfmccall@IN8bio.com

Media Contact
Kimberly Ha
KKH Advisors
917.291.5744
kimberly.ha@kkhadvisors.com