IN8bio Presents Positive Phase 1 Data at TCT 2025, Highlighting Durability of Remissions in High-Risk AML

February 14, 2025

NEW YORK, Feb. 14, 2025 (GLOBE NEWSWIRE) -- February 14, 2025 – IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, yesterday presented Phase 1 data on its allogeneic gamma-delta T cell therapy, INB-100, at the 2025 Transplantation & Cellular Therapy (TCT) Meetings in Hawaii. The data, previously announced, reinforce INB-100's potential to significantly reduce post-transplant relapse in high-risk acute myeloid leukemia (AML) patients, positioning this gamma-delta T cell therapy as a promising approach in hematologic oncology.

The latest findings demonstrate that INB-100 continues to deliver long-term remissions, with no AML patient relapses observed to date with a median follow-up of 20.1 months. The 1-year progression-free survival (PFS) rate across all leukemia patients stands at 90.9%, and 1-year overall survival (OS) is 100%, outperforming real-world historical controls. These data demonstrate that results for INB-100 do not appear to be due to imbalances in patient selection criteria, the performance of the individual clinical centers or driven by specific transplant or lymphodepletion protocols. These data underscore INB-100's potential to reshape post-transplant care by leveraging gamma-delta T cells to enable sustained cancer cell surveillance and long-term remissions.

"AML patients undergoing allogeneic HSCT face high relapse rates with limited post-transplant therapeutic options," said William Ho, Chief Executive Officer and co-founder of IN8bio. "The durability of response and safety profile observed to date with INB-100 support its potential to set a new standard in post-transplant leukemia management."

"Despite decades of progress in transplantation, relapse remains the primary driver of mortality in AML patients post-HSCT. The INB-100 data showing durable remission without maintenance therapy is highly encouraging," said Dr. Michael Bishop, Director of the Hematopoietic Cellular Therapy Program, Director of the David and Etta Jonas Center for Cellular Therapy, and Professor of Medicine at the University of Chicago and IN8bio Scientific Advisory Board member.

Key Phase 1 INB-100 Findings:

- **Zero Relapses in AML Patients:** No relapses observed in any AML patient treated with INB-100, with a median follow-up of over 20 months.
- **Superior 1-Year Survival Rates:** PFS at 90.9%, OS at 100%.
- **Favorable Safety Profile:** No cytokine release syndrome (CRS), neurotoxicity (ICANS), or Dose Limiting Toxicities (DLT's). No treatment-related deaths.
- **Gamma Delta T Cell Persistence and Expansion:** Evidence of in vivo expansion and long-term persistence, reinforcing the therapy's potential to maintain immune surveillance against residual leukemic cells.

With approximately 20,000 new AML cases and ~11,500 deaths annually in the U.S., AML remains an area of high unmet medical need. Post-HSCT relapse occurs in up to 50% of patients, highlighting the urgency for novel, more durable therapeutic approaches. INB-100 harnesses the innate tumor-targeting properties of gamma-delta T cells to improve long-term outcomes, potentially filling a critical treatment gap.

IN8bio is accelerating patient enrollment in the INB-100 program and expects to complete enrollment of the expansion cohort in 2025. The company's FDA discussions confirmed that relapse-free survival (RFS) is an acceptable primary endpoint for a future potentially pivotal randomized controlled trial in AML patients.

IN8bio recently hosted a Key Opinion Leader webinar discussing the latest developments in gamma-delta T cell therapy and the promising INB-100 clinical data. The webinar featured insights including Dr. Michael Bishop. A replay of the February 11, 2025 webinar is accessible here on the company's website.

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.

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