IN8bio Solidifies Position as a Clinical Leader of Gamma-Delta T Cell Therapy in Oncology with 100% of Treated AML Patients in Complete Remission and Receives FDA Guidance for Registrational Trial of INB-100

August 12, 2024

- Received FDA guidance on the registrational path for INB-100 in acute myeloid leukemia (AML), an investigational allogeneic gamma-delta T cell therapy, with IND submission anticipated in Q1 2025.
- Early clinical data from investigator sponsored trials demonstrates prolonged relapse-free survival across both AML and glioblastoma (GBM) programs, compared to current standard-of-care, with both programs advancing to Phase 2 clinical development.
- Solidifying position as a leader in gamma-delta T cell therapy for oncology as the first company to report improvements in relapse-free survival in both solid and hematological cancers with allogeneic or autologous gamma-delta T cells.
- Conference call and webcast to be hosted today at 8:30 a.m. ET. Use this link to participate. A listen-only version of the webcast is available here.

NEW YORK, Aug. 12, 2024 (GLOBE NEWSWIRE) -- **IN8bio, Inc. (Nasdaq: INAB)**, a leading clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies for cancer, today announced updated positive clinical data from both of the Company's Phase 1 investigator-sponsored trials of INB-100 for hematological malignancies and INB-200 for GBM. The Company has also completed a Type B meeting with the FDA and received guidance on the registrational path to advance INB-100 for the treatment of AML.

Every AML patient treated with INB-100 remains in complete remission (CR), and patients across both trials have exceeded expected progression-free survival (PFS) to date. These data continue to demonstrate the broad clinical potential of gamma-delta T cells for difficult-to-treat cancers and provides support for the advancement of these therapies into Phase 2 trials.

As of August 1, 2024, no new relapses have been reported since the clinical updates provided at the American Society of Clinical Oncology (ASCO) and the European Hematology Association (EHA) annual meetings.

"Our gamma-delta T cell therapies, engineered with our industry-leading manufacturing technology, continue to demonstrate their potential to eliminate residual cancer cells and to revolutionize cancer treatment," said William Ho, CEO and co-founder of IN8bio. "The safety profile of gamma-delta T cells has been manageable and well-tolerated across both indications with no significant cell therapy-related toxicities reported to date in any patients across these Phase 1 trials."

Program Details as of August 1, 2024:

INB-100 for AML

- **FDA Guidance on Registrational Program**: Following a Type B meeting with the FDA earlier this summer, IN8bio received regulatory guidance on advancing INB-100 for the treatment of AML as a post-transplant maintenance therapy, with relapse-free survival as the primary endpoint. To date, 100% of AML patients treated with INB-100 are in long-term CR, providing a promising path for the registrational trial. IN8bio plans to submit an Investigational New Drug (IND) application to the FDA in Q1 2025. Pending clearance, the Company could initiate a registrational trial for AML in 2025.
- **100% 1-year Relapse-Free Survival:** All patients dosed in the Phase 1 investigator-sponsored trial continue to demonstrate relapse-free survival beyond one year. These patients are mostly classified as high-risk, a category where ~25% would typically be expected to relapse within 100 days post-transplant and up to 50% by one year.
- **AML Patient Outcomes:** 100% of AML patients remain relapse-free after receiving their dose of INB-100. There have been no new relapses reported since the last update with a data cut-off on May 15, 2024. The previously reported patients with other leukemic diagnoses (ALL and MDS/MPN overlap with concurrent TP53 mutations) who relapsed are still alive. The proposed Phase 2 registrational trial will only include patients with AML, a highly aggressive leukemia with high relapse rates, where Phase 1 results to date have shown the most promising long-term responses.
- **Expansion Cohort:** Enrollment in expansion cohort is ongoing, and all treated patients remain in CR, with several having been evaluated for at least 90 days post-transplant and the longest nearing seven months. Full enrollment of the 10-patient expansion cohort is expected by the end of 2024, with long-term follow up results anticipated in 2025.
- **Gamma-Delta T Cell Persistence:** A significant increase in dose-dependent long-term expansion and persistence of

circulating gamma-delta T cells continues to be observed up to day 365 post-infusion. This marks the first instance of an allogeneic cellular therapy demonstrating both persistence and expansion over this extended time frame. Cell persistence potentially allows for the gamma-delta T cells to conduct longer immune surveillance to prevent relapse.

INB-200 for GBM

- **Novel Cellular Therapy Approach:** IN8bio's proprietary drug-resistant immunotherapy (DRI) technology combines standard-of-care chemotherapy with gene-edited, chemotherapy-resistant gamma-delta T cells. Initial data points to a potential dose response across the three cohorts with dose-escalation ranging from a single dose in cohort 1, three doses in cohort 2, and up to six repeat doses in cohort 3. All patients in cohort 1 eventually relapsed. There have been no new relapses with a range of remission from 9.5 to 37.9 months in cohorts 2 and 3 to date. Multiple patients in these higher repeat dose cohorts have now exceeded the overall survival expected with standard-of-care alone relative to historical data.

- **MGMT-unmethylated GBM patients**: Several patients in this group, who are typically poor responders and generally unresponsive to chemotherapy, have remained in remission longer than expected. Notably, one patient who received six doses of INB-200 has been in remission for over a year. Updated clinical data from this trial is expected to be presented in Q4 2024.

- **INB-400 in Phase 2 trial:** This study is investigating six doses of autologous gamma-delta T cells in front-line GBM treatment in combination with standard-of-care. The trial is actively enrolling and treating patients at multiple leading cancer centers across the United States.

Mr. Ho, also commented, "These therapies take advantage of the gamma-delta T cells' natural ability to target the heterogeneity of cancers, prevent immune escape and disease relapse. Multiple patients have now remained in progression-free remissions longer than expected with many now exceeding expected overall survival, based on historical data. The safety profile and long-term remissions observed with both INB-100 and INB-200, now exceeding three years, across two difficult indications, suggest a significant potential advancement for cellular therapies for cancer. With these compelling results to date, IN8bio stands at the forefront of innovation in oncology and gamma-delta T cell development."

Conference Call Details

IN8bio will host a conference call and webcast today, Monday, August 12, 2024, 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 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 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-400 is in a Phase 2 trial in GBM. Additional programs include Phase 1 trials in solid and hematologic tumors, including INB-200 for GBM and INB-100 for patients with hematologic malignancies undergoing transplantation. 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 continue advancing our gamma-delta T-cell programs; the broad clinical potential of gamma-delta T cell therapies to revolutionize cancer treatment; the ability of INB-100 and INB-200 to target difficult to treat cancers and to continue to demonstrate an improvement in relapse free survival across both AML and GBM; the timing and success of IN8bio's interactions with regulatory agencies, including the FDA; and IN8bio's ability to achieve anticipated milestones, including expected presentations and data readouts from its trials, enrollment of additional patients in its clinical trials, advancement of clinical development plans and submission of INDs. 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 August 8, 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,

Corporate Contact:

IN8bio, Inc.
Glenn Schulman, PharmD, MPH
203.494.7411
gdschulman@IN8bio.com

Investors Contact
Meru Advisors
Lee M. Stern
lstern@meruadvisors.com

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