IN8bio Announces New Data at ASH Showing 100 Percent of Cohort 1 Patients Maintained Durable Complete Response in Ongoing Phase 1 Trial of INB-100

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- *Results from the first cohort of patients with hematological malignancies show patients remained progression free; ongoing durations of response extend beyond 2.5 years (31.9 months)*
- *INB-100 continues to demonstrate a manageable safety profile with no dose-limiting toxicities (DLTs) observed to date*
- *Enrollment for Cohort 2 has been initiated with additional clinical updates expected in 2Q 2023*
- *Company to host conference call to discuss data and recent clinical updates at 8:30 a.m. ET today*

NEW YORK, Dec. 12, 2022 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced updated results from the ongoing Phase 1 trial evaluating INB-100, an allogeneic, gamma-delta T cell therapy, in patients with hematologic malignancies undergoing haploidentical stem cell transplantation (HSCT). The data, featured in a poster presentation at the American Society of Hematology (ASH) 2022 Annual Meeting and Exposition, demonstrate the potential of INB-100 to induce long-term durable responses in patients with high-risk or relapsed acute myeloid leukemia (AML) and other hematologic malignancies.

“While haploidentical stem cell transplantation provides a pathway towards leukemic cures, 50% of transplant patients relapse after one year, with many succumbing to the disease,” 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. “The long-term durable responses, in conjunction with a manageable safety profile, observed in Cohort 1 are very meaningful and highlight the potential of INB-100 to increase the cure rates in patients with AML.”

The poster presented at ASH included efficacy and safety data from Cohort 1 of the ongoing study as of the data cutoff of November 11, 2022. As of December 9, 2022, four patients have received the first dose level (DL) of INB-100 (1×10^6 cells/kg) and remain on study and in remission. Three DL1 patients with at least approximately 18 months and one patient with 3.5 months of follow-up all remain in morphologic complete remission (CR); two patients have remained progression free for more than two years, at 31.9 months and 29.5 months respectively, and a third for nearly a year and a half at 17.8 months. A fourth DL1 patient remains relapse free in CR at 3.5 months and continues to be monitored. Immune system reconstitution through the first 100-days post-treatment demonstrates continued normal function, including observed elevations in T cells, B cells, and gamma-delta T cells.

“These results are encouraging, and reinforce our conviction that INB-100, a one-time allogeneic gamma-delta T cell therapy, has the potential to provide meaningful clinical benefit to patients with AML who face a significant risk of relapse,” said Trishna Goswami, M.D., Chief Medical Officer of IN8bio. “We are excited about the early signals of durable relapse-free survival observed in Cohort 1 in this high-risk patient population and look forward to gaining further insights as we enroll additional patients in Cohort 2 and evaluate INB-100 at a higher dose.”

No DLTs, treatment-related ≥ grade 3 adverse events (AEs) or cytokine release syndrome (CRS) have been observed. Steroid-responsive cutaneous acute Grade 1/2 graft-versus-host disease (GvHD) has been observed in all patients, with one patient experiencing Grade 2 intestinal GvHD. The most common AEs were constipation, cytomegalovirus (CMV) reactivation, emesis, fatigue, and hypomagnesaemia, the majority of which were Grade 1/2.

Two patients have been enrolled and dosed in Cohort 2, evaluating INB-100 at a dose level of 3×10^6 cells/kg. The Company expects to share additional clinical updates from the Phase 1 study of INB-100 in 2Q 2023.

Conference Call Details

IN8bio will host a conference call and webcast today, December 12, 2022, at 8:30 a.m. ET to review the data from the ASH presentation, as well as recent clinical updates. The webcast can be accessed by clicking the link: https://edge.media-server.com/mmc/p/vfodqi28 and can also be accessed on the Events & Presentations page of the Company’s website.

About the INB-100 Phase 1 Trial

The Phase 1 clinical trial (NCT03533816) is a 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 haploidentical 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 is currently conducting two investigator-initiated Phase 1 clinical trials for its lead gamma-delta T cell product candidates: INB-200 for the treatment of newly diagnosed glioblastoma and INB-100 for the treatment of patients with leukemia undergoing hematopoietic stem cell transplantation. IN8bio also has a broad portfolio of preclinical programs focused on addressing other solid tumor types. 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 timing of initiation, progress and scope of clinical trials for IN8bio’s product candidates, including INB-100 and INB-400; the potential of INB-100 to treat and increase the cure rates in patients with high-risk or relapsed acute myeloid leukemia (AML) and other hematologic malignancies; and IN8bio’s ability to achieve planned milestones, including expected data readouts from its trials. 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 the ongoing COVID-19 pandemic 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 10, 2022, 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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