IN8bio Observes Durable Morphologic Complete Responses in Ongoing Phase 1 Clinical Trial of INB-100, an Allogeneic Gamma-Delta T Cell Therapy in High-Risk Leukemia Patients

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- *All three patients from the first cohort of high-risk relapsed acute-myeloid leukemia (AML) patients dosed to-date with INB-100 remain alive and progression-free after at least one year.*
- *Patients remain in morphological complete remission (CR) with two patients over two years and a third over one year post-transplant, respectively.*
- *Safety profile continues to be manageable with no dose-limiting toxicities, no treatment-related Grade 3 or greater adverse events, including graft versus host disease (GvHD), and no cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS).*
- *William Ho, CEO and co-founder of IN8bio, will be discussing these results at the 3rd Annual Gamma-Delta T Therapies Summit, at 4:00 p.m. EDT on July 27, in Boston, MA.*

NEW YORK, July 27, 2022 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on the discovery and development of innovative gamma-delta T cell therapies utilizing its DeltEx platform, provided a clinical update from the ongoing Phase 1 trial of INB-100. This program is an allogeneic, or donor-derived, gamma-delta T cell therapeutic candidate in development for patients with high-risk leukemias undergoing haploidentical hematopoietic stem cell transplant (HSCT). William Ho, Chief Executive Officer of IN8bio, will be discussing these results at the 3rd Annual Gamma-Delta T Therapies Summit, being held July 26-28, in Boston.

“We are excited about the early signals of long-term durable responses from gamma-delta T cell therapy in these high-risk AML patients with complex cytogenetics,” said Trishna Goswami, M.D., Chief Medical Officer of IN8bio. “Despite the up to 51% anticipated one-year relapse rate of the patients enrolled in the trial, all three remain alive and disease free for more than one-year post-transplant. These data are highly encouraging, with the potential to increase the rates of cures in AML patients without significant added toxicities observed to date.”

The Phase 1 clinical trial continues to show positive clinical trends with the first three patients remaining alive and progression-free. Despite multiple cytogenetic abnormalities and a high risk of relapse, these patients remain in remission 26.5, 24.2 and 12.5 months post-transplant, respectively. Immune system reconstitution at six months post-treatment demonstrates continued normal function including observed elevations in T cells, B cells, and gamma-delta T cells. No treatment emergent serious adverse events (SAEs), including graft-vs-host disease (GvHD), cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) have been observed. The clinical trial is ongoing and additional patients have been recruited, with updated data expected in late 2022.

Patient Characteristics*:

Patient	Age/Sex	Cytogenetics	Prior lines of Treatments	Conditioning	Safety Events	Time Post Transplant*
002	54 / female	High-risk AML trisomy 8+ and del7; (NGS: Pathogenic variants detected: M5a, FLT3 TKD, NxPM1, DNMT3A, PTPN11)		Reduced intensity conditioning (RIC)	Gr.2 skin GvHD-resolved	26.5 months
003	45 / female	High-risk AML trisomy 8+ and del7 (NGS: Pathogenic variants detected: IDH2, 47,XX,+8[8]/46,sl,-7[9]/48,sl,+8[3])		RIC	Gr.2 GI GvHD and Gr.2 skin GvHD Remains on Jakafi for skin GvHD	24.2 months
006	66 / male	Relapsed AML s/p 7+3, high risk (NGS: Pathogenic variants detected: NF1, ASXL1, DDX41p.R525H)	Cytarabine + daunorubicin (7+3)	RIC	Gr.2 GvHD-resolved	12.5 months

*As of June 30, 2022

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. Three high-risk AML patients with complex cytogenetics have been treated to-date. 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 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; the potential applications and the success of IN8bio's Phase 1 trial of INB-100; the potential of IN8bio's DeltEx platform to discover and develop innovative product candidates; and IN8bio's ability to achieve planned milestones, including 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; 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 and/or the INB-100 trial; 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 SEC on May 12, 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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