# IN8bio Completes Dose Escalation in Phase 1 Trial of INB-100, a Potential First-in-Class Gamma-Delta T Cell Therapy for the Treatment of Leukemias, and Initiates Enrollment for the Phase 2 Trial of INB-400 in Newly Diagnosed Glioblastoma

October 12, 2023

- *Enrollment is now open in the company-sponsored Phase 2 clinical trial of INB-400 in patients with newly diagnosed glioblastoma multiforme (GBM).*
- *Enrollment completed in the dose escalation phase of the investigator-sponsored trial of INB-100 in leukemia patients with a clinical update expected at the American Society of Hematology (ASH) Annual Meeting.*
- *R&D Day held today, October 12, 2023 (9:00am-12:00pm EDT). Register online for webcast here.*

NEW YORK, Oct. 12, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company focused on innovative gamma-delta T cell therapies, today announced the completion of enrollment in the Phase 1 study of INB-100 in leukemia patients and the initiation of patient enrollment in the Phase 2 clinical trial evaluating INB-400 in newly diagnosed glioblastoma multiforme (GBM).

"These important enrollment milestones reflect our continued pursuit to achieve Cancer Zero by leveraging the power of the immune system to develop therapies to eradicate cancer," said William Ho, Co-founder and CEO. "Our novel, synergistic immunotherapy approach has demonstrated promising early clinical results in patients with unmet medical needs. We look forward to progressing the INB-400 and INB-100 trials to explore the full potential of gamma-delta T cells as a treatment option for patients with both solid and hematological cancers."

**Phase 1 Clinical Trial of INB-100 in Leukemia**

Enrollment in the dose escalation phase of the Phase 1 clinical trial (NCT03533816) of INB-100 is now closed. This clinical trial assesses the safety of allogeneic gamma-delta T cells from haploidentical related donors that have been expanded and activated *ex vivo* and administered systemically to patients with leukemia following hematopoietic stem cell transplantation (HSCT). The primary endpoints of this trial are safety and tolerability, and secondary endpoints include rates of graft versus host disease (GvHD), relapse rate and OS.

In April 2023, the Company presented data at the 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) showing that 100% of evaluable patients (n=7) treated with INB-100 remained alive, progression-free, and in durable complete remission (CR). As of April 21, 2023, all evaluable patients across Dose Levels 1 and 2 remained on study and in CR, with one patient remaining progression free for over 3 years. Additional treated patients have remained progression free for 33.9, 22.2, 7.8, 5.8, 5.6 and 2.6 months, respectively. A clinical update with additional enrolled patients will be presented at the 65th ASH Annual Meeting being held December 9-12, 2023 in San Diego, CA.

**Phase 2 Clinical Trial of INB-400 in GBM**

The Phase 2 clinical trial of INB-400 (NCT05664243), an autologous, genetically engineered gamma-delta T cell therapy, is open for enrollment and plans to enroll approximately 40 patients in "Arm A" of the study. The primary endpoint of the study is 12-month overall survival (OS) rate, and key secondary endpoints include tolerability, progression-free survival (PFS), overall response rate (ORR) and time to progression (TTP). The University of Louisville and The Cleveland Clinic are the first clinical sites activated to enroll patients.

INB-400 was granted Orphan Drug Designation by the FDA in April 2023, marking the first genetically modified gamma-delta T cell therapy to receive this regulatory designation. GBM remains a significant unmet need, treatment options and associated outcomes for GBM, a highly aggressive and difficult-to-treat brain cancer, have remained largely unchanged for more than 18 years, with a median progression-free survival of 6-7 months and overall survival of 14-16 months.

**About INB-400**
INB-400 is IN8bio's DeltEx chemotherapy resistant autologous and allogeneic drug-resistant immunotherapy (DRI) technology. Allogeneic INB-400 will expand the application of DRI gamma-delta T cells into other solid tumor types through the development of allogeneic or "off-the-shelf" DeltEx DRI technology.

**About INB-100**
INB-100, IN8bio's DeltEx Allo, is an allogeneic product candidate, initially developed for the treatment of patients with hematologic malignancies undergoing hematopoietic bone marrow transplantation (HSCT). It is currently being evaluated in a Phase 1 dose escalation clinical trial, marking the first clinical trial of an expanded and activated allogeneic gamma-delta T cell immunotherapy.

**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 hematologic malignancies undergoing haploidentical hematopoietic stem cell transplantation. IN8bio is initiating enrollment for a company-sponsored multi-center Phase 2 clinical trial of INB-400 in newly diagnosed glioblastoma, which received IND clearance in late 2022. IN8bio also has a broad portfolio of preclinical programs focused on addressing other hematological and solid tumor cancers. 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 development and continued progress and success of our preclinical and clinical trials and programs and product candidates; the timing of initiation, progress (including as to enrollment) and scope of clinical trials, including for INB-100 and INB-400; the success of gamma delta T cells as a treatment option for patients with both solid and hematological cancers; IN8bio's progress towards and achievement of its goal of "Cancer Zero"; and IN8bio's ability to achieve anticipated milestones, including expected data readouts from its trials, enrollment of additional patients in its clinical trials, advancement of clinical development plans and to develop new preclinical programs. 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 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. These and other factors 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 10, 2023, 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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