IN8bio Announces Clinical Pipeline Prioritization to Focus on INB-100 for Acute Myeloid Leukemia

September 4, 2024

- ***Top Priority Clinical Program:*** *Working to drive significant value creation with INB-100 for AML; ongoing trial is actively enrolling additional patients into the expansion cohort to further support the observed 100% progression-free survival in AML patients as of August 30, 2024.*
- *Suspending enrollment of Phase 2 clinical trial of INB-400 in newly diagnosed GBM; will continue to monitor patients for long-term remissions and overall survival in both INB-400 and INB-200 at UAB.*
- *Company to preserve its cash resources with anticipated clinical cost savings and a workforce reduction of 49%, which is expected to be completed in 3Q24.*

NEW YORK, Sept. 04, 2024 (GLOBE NEWSWIRE) -- **IN8bio, Inc. (Nasdaq: INAB)**, a leading clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies for cancer, today announced a plan to optimize its resource allocation through a pipeline prioritization and a workforce reduction of approximately 49%. The Company will focus on generating robust clinical data from INB-100, the ongoing investigator-sponsored Phase 1 clinical trial of acute myeloid leukemia (AML), to further de-risk the registrational pathway and affirm the 100% one-year progression-free survival observed to date in this patient population.

The Company will suspend its glioblastoma (GBM) development program while continuing to monitor patients in the Phase 1 INB-200 clinical trial and those enrolled in the Phase 2 INB-400 clinical trial. INB-200 has completed patient treatment with up to six repeat doses and further patient enrollment in the INB-400 trial is on hold while the Company explores potential partnership opportunities for the solid tumor program.

“The data across both of our INB-100 and INB-200 clinical programs remain positive and robust. We are committed to building upon the data for INB-100 in AML, and we are making the difficult decision to advance fewer pipeline programs, reduce our spend and focus on key milestones that can help to generate near-term interest and value creation,” said William Ho, Chief Executive Officer and co-founder. “These are hard but necessary steps to enable us to continue developing these novel cellular immunotherapies that are demonstrating signs of clinical activity in difficult cancer patients. We are excited to focus on INB-100 as IN8bio and its investigators believe patient outcomes in its trial to date are surpassing that of similar leukemia patients, including those with AML undergoing haploidentical transplantation without receiving INB-100. I want to express my gratitude to all our employees, including those departing IN8bio today, for their contributions towards our mission of Cancer Zero.”

Portfolio prioritization

INB-100 for AML

With additional funding, the INB-100 trial will continue to enroll patients in the expansion cohort with a new target total enrollment of approximately 25 patients at the recommended Phase 2 dose. IN8bio expects to complete this additional enrollment in the first half of 2025, with long-term follow-up results anticipated in late 2025 and in 2026.

IN8bio had a Type B meeting with the FDA earlier this summer where the Company 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 affirm the improvements in relapse free and overall survival observed to date and to further de-risk a future registrational randomized control trial, IN8bio will also seek to add a control cohort to prospectively assess leukemia patients and enable comparison between patients receiving INB-100 to those who only receive standard haplotransplantation.

As of August 30, 2024, 100% of AML patients remain relapse-free after receiving their dose of INB-100 after a median follow-up of 18.7 months. The previously reported patients with other leukemic diagnoses (ALL and MDS/MPN overlap with concurrent TP53 mutations) who relapsed have since died of progression. There have been no new relapses reported since the last update.

INB-200 and INB-400

The Company has suspended patient enrollment in the INB-400 Phase 2 clinical trial for newly diagnosed GBM while it explores partnership opportunities for the program. IN8bio will continue to monitor patients previously treated in the fully enrolled INB-200 clinical trial as well as any patients that have been enrolled and are undergoing treatment in the INB-400 Phase 2 clinical trial.

Workforce Reduction

In conjunction with its pipeline prioritization, IN8bio is implementing a workforce reduction of approximately 49% of its current workforce, across all functional areas and at both its New York City and Birmingham, Alabama sites, along with cash compensation reductions implemented across the executive management team and the Company’s board of directors. IN8bio expects to incur one-time costs of approximately $0.3 million in connection with the workforce reduction, of which nearly all are cash expenditures related to severance. Such costs are expected to be incurred in the third quarter of 2024.

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 allogenic 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 GBM. 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: the ability of INB-100 for AML to drive significant value creation; IN8bio's ability to preserve its cash resources, achieve clinical cost savings and optimize its resource allocation; the timing and impact of IN8bio's workforce reduction; IN8bio's ability to find partnership opportunities for the GBM clinical development program; the ability of IN8bio's key milestones to help to generate near-term interest and value creation; IN8bio's ability to continue developing novel gamma-delta T cell therapies; IN8bio's ability to receive additional funding; 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. 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; 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,

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