IN8bio Announces FDA Clearance to Initiate a Phase 2 Clinical Trial of INB-400 Gamma-Delta T Cells for Glioblastoma

December 8, 2022

- Phase 2 clinical trial initiation expected in 2023
- Company to host conference call to discuss recent clinical updates, including updated data from the Phase 1 clinical trial of INB-100 being presented at the American Society of Hematology (ASH) on Monday, December 12th at 8:30 a.m. ET

NEW YORK, Dec. 08, 2022 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate a Phase 2 clinical trial of a genetically modified autologous gamma-delta T cell therapy (INB-400) targeting newly diagnosed glioblastoma (GBM). The study will assess the safety, efficacy and tolerability of genetically modified DeltEx drug-resistant immunotherapy (DRI) cells at leading medical centers across the United States.

“Obtaining clearance to begin the INB-400 Phase 2 clinical trial is an important milestone for IN8bio as it is our first company-sponsored IND. This milestone demonstrates the clinical, regulatory and CMC capabilities of the IN8bio team in continuing to advance novel gamma-delta T cell therapies to cancer patients,” said William Ho, Chief Executive Officer and co-founder of IN8bio. “The clinical program is designed to eventually assess DeltEx DRI with both autologous and allogeneic approaches in both the front-line and relapsed setting. We believe the insights we unlock in GBM will be essential as we apply our DeltEx platform across multiple solid tumor cancers.”

The Phase 2 clinical trial will commence with the enrollment of newly diagnosed GBM patients, with the initial arm assessing autologously derived MGMT-modified gamma-delta T cells. In line with recent FDA guidance, the Company is planning to expand the trial to include an allogeneic DeltEx DRI drug product in relapsed refractory GBM and potentially the frontline setting. The primary endpoint of the study is overall survival (OS); secondary endpoints include tolerability, progression-free survival (PFS), overall response rate (ORR) and time to progression (TTP).

Conference Call Details

IN8bio will host a conference call and webcast on Monday, December 12th at 8:30 a.m. ET to review recent clinical updates, including updated data from the Phase 1 clinical trial of INB-100 being presented at ASH. 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 INB-400

INB-400 is IN8bio’s DeltEx chemotherapy resistant autologous and allogeneic 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 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-400; the Company’s plan to expand the INB-400 clinical trial to include an allogeneic DeltEx DRI drug product in relapsed refractory and potentially the frontline setting; the potential of IN8bio’s DeltEx platform to discover and develop innovative product candidates; 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, 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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