IN8bio Receives FDA Orphan Drug Designation for INB-400/410 for the Treatment of Newly Diagnosed Glioblastoma

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- *First-ever orphan drug designation for genetically modified gamma-delta T cell therapies*
- *This orphan drug designation offers potential 7-year market exclusivity for both autologous (INB-400) and allogeneic (INB-410) candidates*
- *INB-400 is an autologous, genetically engineered gamma-delta T cell therapy that was recently cleared by the FDA for a Phase 2 trial targeting newly diagnosed glioblastoma multiforme (GBM)*

NEW YORK, April 25, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on innovative gamma-delta T cell therapies, announces FDA orphan drug designation for INB-400 and INB-410, covering a broad range of malignant glioma treatments, including newly diagnosed GBM. As an industry leader in gamma-delta T cell development, this milestone marks the first genetically modified gamma-delta T cell therapy to receive this designation, which offers potential incentives such as 7-year market exclusivity.

In December 2022, the FDA cleared IN8bio's investigational new drug application (IND) for a Phase 2 clinical trial in newly diagnosed GBM for INB-400. With Institutional Review Board (IRB) review and site initiation ongoing, patient enrollment is expected to begin in the second half of 2023.

"Our goal is to achieve our Mission of Cancer Zero by eradicating cancer cells and improving patient outcomes," said IN8bio CEO and co-founder, William Ho. "Our novel approach combines engineered, chemo-resistant gamma-delta T cells with standard-of-care treatments to amplify immune signals, maximize tumor killing, and eliminate more cancer cells. We eagerly anticipate enrolling our first Phase 2 patients for INB-400 later this year."

GBM, a highly aggressive and difficult-to-treat brain cancer, has remained largely unchanged in treatment options for over 18 years, with a median progression-free survival of 6-7 months and overall survival of 14-16 months.

Orphan drug designation benefits IN8bio through incentives such as potential additional market exclusivity following approval, tax credits on qualified US clinical trials, eligibility for orphan drug grants, and exemption from certain fees. With this milestone, IN8bio continues to progress its pipeline programs and will provide further clinical updates on its pipeline at medical meetings throughout the year.

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 is initiating INB-400, a company-sponsored Phase 2 clinical trial in newly diagnosed glioblastoma following IND clearance in late 2022. 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 development and continued progress of the INB-400 and INB-410 programs, including the intended incentives conferred by orphan drug designation; the timing of initiation, progress and scope of clinical trials; and IN8bio’s ability to achieve anticipated milestones, including expected data readouts from its trials, enrollment of additional patients in its clinical trials and 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, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 30, 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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