Inhibrx Initiates a Registration-Enabling Trial of INBRX-101 in AATD and Announces Lift of Partial Clinical Hold on INBRX-109 DR5 Agonist Trials

SAN DIEGO, April 26, 2023 /PRNewswire/ -- Inhibrx, Inc. (Nasdaq: INBX), a clinical-stage biopharmaceutical company dedicated to the development of therapeutics for oncology and rare diseases, announced today that it has initiated a registration-enabling trial for INBRX-101, an optimized recombinant human AAT-Fc fusion protein, for treatment of patients with emphysema due to alpha-1 antitrypsin deficiency (AATD). Additionally, the Company announced that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on studies evaluating its death-receptor 5 (DR5) agonist, INBRX-109.

INBRX-101

The ElevAATe trial is designed as a randomized, controlled, double-blind, head-to-head superiority study examining INBRX-101 against plasma-derived AAT (pdAAT). The study design is as follows: 36 patients dosed every three weeks with INBRX-101 at 120 mg/kg, 36 patients dosed every four weeks with INBRX-101 at 120 mg/kg, and 18 patients dosed weekly with pdAAT at the FDA-approved dose. The treatment period is 32 weeks and will be conducted at approximately 35 sites in the United States, Australia and New Zealand.

The primary endpoint of the trial is the mean change in the average functional AAT (fAAT) concentration as measured by anti-neutrophil elastase capacity (ANEC) from baseline to average serum trough fAAT concentration at steady state ($C_{trough,ss}$). Secondary endpoints are a comparison of the mean change in fAAT concentration from baseline to fAAT average concentration at steady state ($C_{avg,ss}$), and the percentage of days with fAAT above the lower limit of the normal range during steady-state dosing. A bronchoscopy sub-study of approximately 30 patients will also run at designated sites.

The initial read-out from the ElevAATe trial is expected to occur in late 2024.

INBRX-109

In March 2023, the Company announced the pause in patient enrollment for the INBRX-109 (DR5 agonist) trials as a result of the pre-defined stopping rules built into the Phase 2 protocol. This did not impact active patients who were already on treatment and remained on the trial. With data from over 200 patients dosed with INBRX-109 to date, the Company was able to more precisely identify elderly individuals with fatty liver disease as the at-risk population for severe liver toxicity. As a result, the Company amended its protocol to include the Hepatic Steatosis Index (HSI) as part of the screening criteria.

In April 2023, the FDA lifted the partial clinical hold. Patient enrollment is expected to resume next month. Phase 1 combination cohorts are expected to begin reading out by the end of 2023 and data from the registration-enabling trial in unresectable or metastatic conventional chondrosarcoma is expected during the second half of 2024.

About INBRX-101 and AATD

INBRX-101 is a precisely engineered recombinant human AAT-Fc fusion protein designed to safely achieve and maintain levels of alpha-1 antitrypsin (AAT) found in healthy individuals with the potential for a less frequent dosing interval compared to the weekly infusion interval of the currently available plasma-derived AAT therapies.

AATD is an inherited orphan disease affecting an estimated 100,000 patients in the United States. AATD is characterized by deficient levels of the AAT protein, which causes loss of lung tissue and function and decreased life expectancy. Augmentation therapy with plasma-derived AAT is the current standard of care but does not maintain patients in the normal AAT range, requires frequent and inconvenient once-weekly IV dosing, and relies on plasma collection practices that might not be sustainable.

Data from the Phase 1 multiple ascending dose study of INBRX-101 at 40, 80 and 120 mg/kg IV every three weeks showed the expected accumulation of functional AAT levels and the ability to achieve fully normal functional AAT levels in severely deficient AATD patients. Based on PK modeling, accumulation is expected to continue following subsequent doses and reach steady state after a total of approximately five to six consecutive doses, administered every three or four weeks.

Treatment was well tolerated with no severe or serious adverse events related to the study drug. Drug-related adverse events were predominantly mild and those few that were moderate in severity were all transient and reversible, with minimal or no symptomatic care. No safety-related or PK/PD-related signs of neutralizing anti-drug antibodies were observed.

In March 2022, the FDA granted orphan-drug designation for INBRX-101 for the treatment of AATD.

About INBRX-109 and Chondrosarcoma

INBRX-109 is a precision-engineered, tetravalent death receptor 5 (DR5) agonist antibody designed to exploit the tumor-biased cell death induced by DR5 activation.

Chondrosarcoma is an orphan bone cancer with approximately 2,800 new patients diagnosed annually in the United States and the EU. There are currently no therapeutics approved for the treatment of chondrosarcoma.

In 2021, the FDA granted Fast Track designation to INBRX-109 for the treatment of patients with unresectable or metastatic conventional chondrosarcoma and orphan-drug designation to INBRX-109 for chondrosarcoma in the United States.

In June 2021, Inhibrx initiated a randomized, blinded, placebo-controlled, registration-enabling Phase 2 trial of INBRX-109 in conventional chondrosarcoma. This trial, in addition to the additional Phase 1 cohorts examining INBRX-109 in combination with certain chemotherapies, are currently ongoing.

About Inhibrx, Inc.

Inhibrx is a clinical-stage biopharmaceutical company focused on developing a broad pipeline of novel biologic therapeutic candidates in oncology and orphan diseases. Inhibrx utilizes diverse methods of protein engineering to address the specific requirements of complex target and disease biology, including its proprietary protein engineering platforms. Inhibrx has collaborations with 2seventy bio (formerly bluebird bio), Bristol-Myers Squibb and Chiesi. For more information, please visit www.inhibrx.com.

Forward-Looking Statements

Inhibrx cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on Inhibrx's current beliefs and expectations. Forward-looking statements include, but are not limited to, statements regarding: Inhibrx's and its investigators' judgments and beliefs regarding the observed safety and efficacy to date of its therapeutic candidates, INBRX-101 and INBRX-109, discussions with and beliefs regarding future action by the FDA, including any potential accelerated regulatory pathway, whether a trial is registration-enabling, evaluations and observations of FDA discussions, statements and beliefs regarding the current standard of care for AAT and the sustainability of current plasma collection practices, future clinical development, application and dosage of INBRX-101 or INBRX-109 and any presumption of or implied presumption of positive results from pre-clinical studies, Phase 1 clinical trials, or later clinical trials. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Inhibrx's business, including, without limitation, risks and uncertainties regarding: the initiation, timing, progress and results of its preclinical studies and clinical trials, and its research and development programs; its ability to advance therapeutic candidates into, and successfully complete, clinical trials; its interpretation of initial, interim or preliminary data from its clinical trials, including interpretations regarding disease control and disease response; the timing or likelihood of regulatory filings and approvals; the successful commercialization of its therapeutic candidates, if approved; the pricing, coverage and reimbursement of its therapeutic candidates, if approved; its ability to utilize its technology platform to generate and advance additional therapeutic candidates; the implementation of its business model and strategic plans for its business and therapeutic candidates; its ability to successfully manufacture therapeutic candidates for clinical trials and commercial use, if approved; its ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the scope of protection it is able to establish and maintain for intellectual property rights covering its therapeutic candidates; its ability to enter into strategic partnerships and the potential benefits of these partnerships; its estimates regarding expenses, capital requirements and needs for additional financing and financial performance; and other risks described from time to time in Inhibrx's filings with the U.S. Securities and Exchange Commission (the SEC), including under the heading "Risk Factors" in Inhibrx's Annual Report on Form 10-K filed with the SEC on March 6, 2023 and subsequently filed reports. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Inhibrx undertakes no obligation to update these statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This press release contains estimates and other statistical data made by independent parties and by Inhibrx. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

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