Inhibrx Retains Rights to INBRX-101 for the Treatment of Alpha-1 Antitrypsin Deficiency Outside of the United States and Canada

SAN DIEGO, Sept. 19, 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 Chiesi Farmaceutici S.p.A ("Chiesi") declined to exercise its option for the ex-North American rights to develop and commercialize INBRX-101 for the treatment of patients with emphysema due to Alpha-1 Antitrypsin Deficiency ("AATD").

Inhibrx's delivery of the European Medicines Agency ("EMA") scientific advice to Chiesi triggered a 60-day option period to obtain an exclusive license to develop and commercialize INBRX-101 for the treatment of patients with AATD outside of the United States and Canada. On September 18, 2023, Chiesi notified Inhibrx it was declining this option.

"We believe Inhibrx is now optimally positioned with full global rights to INBRX-101. This enables broader strategic optionality, including potentially launching Graft versus Host Disease ("GvHD") as a first indication in Europe and Japan. The number of allogeneic transplants in Europe and Japan are double that of the United States and since GvHD therapies have a clear reimbursement path in these markets, we see this as a significant opportunity to help more patients desperately in need," said Mark Lappe, CEO of Inhibrx.

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 and 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.

Inhibrx is currently conducting the ElevAATe trial, which is designed as a randomized, controlled, double-blind, head-to-head superiority study examining INBRX-101 against plasma-derived AAT. The primary endpoint of the trial is the mean change in the average functional AAT ("fAAT") concentration as measured by anti-neutrophil elastase capacity 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.

The initial read-out from the ElevAATe trial is expected to occur in late 2024 and the Company plans to meet with the FDA following completion of that study.

About INBRX-101 and GvHD

Hematopoietic stem cell transplants ("HSCTs") provide an often-curative option for many patients with hematological and oncological conditions, with multiple myeloma, Non-Hodgkin lymphoma, and acute myelogenous leukemia being the most common diseases requiring an HSCT treatment. GvHD is a significant problem that can occur post-surgery, usually after an allogeneic transplant, where the cells donated during the transplant see the recipient's body as foreign and attack the body.

Strong clinical data and established guidelines for the use of AAT therapy already exist for acute cases of GvHD. Current clinical data for plasma-derived AAT therapies for the treatment of GvHD show promising response rates and favorable safety profiles over approved therapies, but half-life of the therapies is short and therefore requires dosing every two to four days. Based on the observed favorable safety profile of INBRX-101 to date coupled with its extended half-life, we believe INBRX-101 has the potential for greater efficacy due to the ability to dose at higher levels less frequently, while also eliminating the pathogenic risk from plasma-derived products, which can be life threatening in immunocompromised patients susceptible to infection.

Inhibrx plans to initiate studies for both acute and chronic GvHD during the first half of 2024.

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. 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 candidate, INBRX-101, 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 GvHD and the sustainability of current plasma collection practices, potential payor reimbursement, future clinical development, application and dosage of INBRX-101 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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