Inhibrx Announces Opportunity for Accelerated Approval Pathway on Functional AAT Serum Levels for INBRX-101 in AATD and Announces Bronchoalveolar Lavage Fluid Detection Results from the Phase 1 Study

SAN DIEGO, Oct. 4, 2022 /PRNewswire/ -- Inhibrx, Inc. (Nasdaq: INBX), a clinical-stage biopharmaceutical company dedicated to the development of therapeutics for oncology and rare diseases, announced today that, based on discussions with the U.S. Food and Drug Administration (FDA), there is potential to pursue an accelerated approval in the U.S. for INBRX-101, an optimized recombinant human AAT-Fc fusion protein, in patients with emphysema due to alpha-1 antitrypsin deficiency (AATD) using functional alpha-1 antitrypsin (AAT) serum levels as the surrogate endpoint. Inhibrx also announced the detection of INBRX-101 in the bronchoalveolar lavage fluid (BALF) samples from all AATD patients tested in the Phase 1 study.

Inhibrx plans to initiate in the first quarter of 2023 a potential registration-enabling clinical trial using functional AAT as a surrogate endpoint with the intent to submit for regulatory approval under the FDA's Accelerated Approval Program. The FDA expressed support to collaborate and work with Inhibrx to address the regulatory challenges associated with AATD drug development. The FDA emphasized the importance of being able to demonstrate INBRX-101's ability to maintain a trough level within the normal range of AAT in healthy individuals. Based on data from the completed Phase 1 study of INBRX-101, the dosing of INBRX-101 every three or four weeks in patients with AATD is predicted to maintain patients above the lower threshold of the normal range and achieve an average level of functional AAT that approximates that of healthy non-deficient (MM genotype) adults.

The FDA also requested additional data on the correlation between functional AAT levels and the clinical benefit in AATD to further support serum AAT levels as a surrogate endpoint that is reasonably likely to predict clinical benefit, the prerequisite for accelerated approval. Inhibrx intends to collaborate with experts in the field and the Alpha-1 Foundation to illustrate, based on existing registry, health records and published data, that increased functional AAT levels are reasonably likely to predict clinical benefit in AATD patients.

The accelerated approval pathway can be used for a drug intended for a serious or life-threatening illness that provides a meaningful therapeutic advantage over existing treatments. Accelerated approval can be based on the drug's effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients, with a required post-approval trial(s) to verify that the drug provides the expected clinical benefit.

Independent of FDA discussions, Inhibrx also completed analysis and reported BALF data demonstrating the post-dose presence of INBRX-101 in every patient and in all three lobes of the lung collected from each of these patients. This data showed emerging evidence of a dose dependent increase of INBRX-101 lung exposure. These BALF samples were from eleven AATD patients in the 80mg/kg and 120mg/kg multiple ascending dose cohorts of the Phase 1 study and were analyzed using a proprietary and validated mass spectrometry assay developed by Inhibrx to detect INBRX-101 specifically.

Additionally, on October 3, 2022, the Company amended the milestone terms of the last remaining tranche under its loan and security agreement with Oxford Finance LLC to provide for the funding of $30.0 million upon the announcement of the regulatory path for INBRX-101 rather than upon the initiation of a potential registration-enabling clinical trial of INBRX-101. The Company has thirty days from this announcement to initiate this draw.

The Company will host a live webcast presentation today at 5:30 a.m. PT to further discuss the regulatory path and to provide an update on the clinical pipeline.

About the Conference Call

Investors may join via the web: https://app.webinar.net/8GArp0rQd3z or may listen to the call by dialing (1-877-870-4263). Please refer to Inhibrx, Inc. or confirmation code 10171898 when calling in. Following the webcast, the presentation may be accessed through a link on the investors section of Inhibrx's website at https://inhibrx.investorroom.com/events-and-presentations. The webcast will be available for 60 days following the event. Following the presentation, Inhibrx will update its corporate presentation within the "Investors" section of its website at www.inhibrx.com.

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, or 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.

Alpha-1 antitrypsin deficiency, or 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 Inhibrx, Inc.

Inhibrx is a clinical-stage biotechnology 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 sdAb platform. 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. These 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, 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 and any presumption of or implied presumption of positive results from pre-clinical studies or 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; its expectations regarding the impact of the COVID-19 pandemic on its business; and other risks described 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 for the year ended December 31, 2021, as filed with the SEC on February 28, 2022, as well as its Quarterly Reports on Form 10-Q, and supplemented from time to time by its Current Reports on Form 8-K. 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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