

Inhibrx Granted Fast Track Designation for INBRX-101 for the Treatment of Alpha-1 Antitrypsin Deficiency

SAN DIEGO, May 30, 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 the U.S. Food and Drug Administration (FDA) granted Fast Track designation to INBRX-101, an optimized recombinant human AAT-Fc fusion protein, for the treatment of patients with emphysema due to alpha-1 antitrypsin deficiency (AATD).

[Fast Track](#) designation is granted by the FDA upon the request of the sponsor to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening diseases. Depending upon the stage of the product's development, the sponsor must also provide FDA with nonclinical or clinical data to demonstrate the drug's potential to address unmet medical needs for such a disease or condition. Investigational drug products with Fast Track designation may benefit from early and frequent communication with the FDA, and are eligible for rolling submission and FDA review of its future marketing application.

The ElevAATe study (NCT05856331) is a registration-enabling trial for INBRX-101 initiated in April 2023 and is designed as a randomized, controlled, double-blind, head-to-head superiority study examining INBRX-101 against plasma-derived AAT. The primary endpoint 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}).

The initial read-out from the ElevAATe trial is expected to occur in late 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 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 candidate, INBRX-101, discussions with and beliefs regarding future action by the FDA, the degree to which and whether a Fast Track designation will ultimately expedite approval, 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 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.

Investor and Media Contact:

Kelly Deck, CFO

kelly@inhibrx.com

858-795-4260

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