

# Inhibrx Granted Fast Track Designation for INBRX-109 for the Treatment of Unresectable or Metastatic Conventional Chondrosarcoma Patients

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## Registration-enabling study expected to begin dosing in the second or third quarter of this year

SAN DIEGO, Jan. 13, 2021 /PRNewswire/ -- Inhibrx, Inc. (Inhibrx), a clinical-stage biotechnology company with a broad pipeline of biotherapeutics in development, announced today the U.S. Food and Drug Administration (FDA) granted Fast Track designation to INBRX-109 for the treatment of patients with unresectable or metastatic conventional chondrosarcoma. INBRX-109 is a precisely engineered tetravalent single domain antibody (sdAb)-based therapeutic candidate that agonizes death receptor 5 (DR5) to induce tumor selective programmed cell death.

[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 designation was granted to INBRX-109 based on preliminary data from the chondrosarcoma expansion cohort of the Phase 1 clinical trial of INBRX-109.

"There are currently no approved agents for the treatment of unresectable or metastatic conventional chondrosarcoma, and we are excited about the potential of this treatment to meaningfully improve the outcome for patients," said Mark Lappe, CEO of Inhibrx. "We look forward to working closely with the FDA throughout the clinical development of INBRX-109."

A potential registration-enabling Phase 2 study of INBRX-109 has been discussed with the FDA and will be designed as a randomized, blinded, placebo-controlled study in unresectable or metastatic conventional chondrosarcoma with progression-free survival as the primary endpoint. Inhibrx expects to start dosing patients in this potentially registration-enabling study in the second or third quarter of this year.

## About the Inhibrx sdAb Platform

Inhibrx utilizes diverse methods of protein engineering in the construction of therapeutic candidates that can address the specific requirements of complex target and disease biology. A key tool for this effort is the Inhibrx proprietary sdAb platform, which enables the development of therapeutic candidates with attributes superior to other monoclonal antibody and fusion protein approaches. This platform allows the combination of multiple binding units in a single molecule, enabling the creation of therapeutic candidates with defined valency or multiple specificities, potentially capable of enhanced cell signaling or conditional activation. An additional benefit of this platform, these optimized, multi-functional entities can be manufactured using the established processes that are commonly used to produce therapeutic proteins.

Initially, Inhibrx is pursuing targets with early clinical validation, such as DR5, where other therapeutics have demonstrated liabilities. In addition, Inhibrx is developing a portfolio of sdAb based therapeutic candidates in a variety of indications for both known and novel targets.

## About Inhibrx, Inc.

Inhibrx is a clinical-stage biotechnology company focused on developing a broad pipeline of biologic therapeutic candidates. Inhibrx utilizes diverse methods of protein engineering to therapeutically address the specific requirements of complex target and disease biology, including its proprietary sdAb platform. The Inhibrx pipeline is currently focused on oncology and orphan diseases. Inhibrx has collaborations with bluebird bio, Celgene and Chiesi. For more information, please visit [www.inhibrx.com](http://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 or potential safety and efficacy of its therapeutic candidates in clinical trials and beliefs regarding the future clinical development of INBRX-109, including its ability to conduct any registration-enabling study. 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 Form 10-Q for the quarter ended September 30, 2020 filed with the SEC on November 13, 2020 and any subsequent filings with the SEC. 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.

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