European Medicines Agency Grants Orphan Drug Designation to INBRX-109 for the Treatment of Chondrosarcoma

SAN DIEGO, Aug. 15, 2022 /PRNewswire/ -- Inhibrx, Inc. (Nasdaq: INBX), a biotechnology company with four clinical programs in development and a strong emerging pipeline, today announced that the European Commission ("EC"), based on a positive opinion issued by the European Medicines Agency ("EMA"), has granted orphan medicinal product designation to INBRX-109 for the treatment of chondrosarcoma.

"We are highly optimistic about the potential of INBRX-109 in chondrosarcoma to address a high unmet medical need," said Inhibrx Chief Executive Officer, Mark Lappe. "The positive opinion issued by the EMA is excellent news and acknowledges the potential of INBRX-109 as a treatment for patients throughout Europe who suffer from this debilitating, rare condition."

The EC grants orphan designation to drugs and biologics intended for the safe and effective treatment, prevention, or diagnosis of a disease that is life-threatening or chronically debilitating impacting fewer than five in 10,000 patients in the European Union ("EU"). Orphan drug designation in the EU can provide certain benefits, including reduced regulatory fees, clinical protocol assistance and the potential for up to ten years of market exclusivity following regulatory approval.

About Chondrosarcoma

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.

About INBRX-109

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.

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, potential registration-enabling Phase 2 trial of INBRX-109 in conventional chondrosarcoma, which is currently ongoing.

In November 2021, Inhibrx provided updated results from its ongoing Phase 1 clinical trial evaluating the efficacy and safety of INBRX-109 in patients with conventional chondrosarcoma. Preliminary disease control was observed in 16 of the 18 evaluable patients (89%) measured by RECISTv1.1, with two of the 18 achieving partial responses (11%). Based on preliminary results of the ongoing Phase 1 trial at that time, the median progression-free survival (PFS) was 7.4 months, and the median overall survival had not been reached. Three patients had exceeded 61 weeks on treatment with INBRX-109, with 77 weeks being the longest duration of stable disease observed at that time.

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 strength of Inhibrx's pipeline, any future potential or observed to date safety and efficacy of its therapeutic candidate, INBRX-109, discussions with and beliefs regarding future action by the FDA or EMA, and statements and beliefs regarding the clinical development of

INBRX-109 including statements indicating that the Phase 2 trial is registration-enabling, potential benefits of the orphan drug-designation and any presumption of positive results from Phase 1 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 from time to time in the "Risk Factors" section of its filings with the U.S. Securities and Exchange Commission, or the SEC, including those described in its 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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