Inhibrx Biosciences Announces Preliminary Data from the Phase 1 Trial of ozekibart (INBRX-109) for the Treatment of Colorectal Cancer

SAN DIEGO, Jan. 21, 2025 /PRNewswire/ -- Inhibrx Biosciences, Inc. (Nasdaq: INBX) ("Inhibrx" or the "Company"), a clinical-stage biopharmaceutical company focused on developing therapeutics for oncology and rare diseases, today announced preliminary efficacy and safety data from the Phase 1 trial of ozekibart (INBRX-109) in combination with FOLFIRI for the treatment of advanced or metastatic, unresectable colorectal adenocarcinoma (CRC). These results were presented at the American Society of Clinical Oncology (ASCO) Gastrointestinal Annual Cancers Symposium.

Efficacy was assessed in 10 of the 13 patients who received at least one dose of ozekibart, based on RECIST v1.1 criteria. Results demonstrated one complete response (CR), three partial responses (PR), and six cases of stable disease (SD). Durable disease control lasting ≥180 days was observed in 46.2% of patients, with a median progression-free survival (PFS) of 7.85 months. All patients had received at least one prior line of systemic therapy (median: two; range: 1–6). Notably, the patient achieving a CR had undergone three prior lines of therapy, and two PRs occurred in patients who had failed prior FOLFIRI-based treatments.

Ozekibart-related treatment-emergent adverse events (TEAEs) were reported in 84.6% of patients, with most being grade 1 or 2 in severity. Grade ≥3 TEAEs were observed in 30.8% of patients. The most common ozekibart-related TEAEs included nausea, increased alanine aminotransferase, diarrhea, and fatigue, with the majority being low-grade.

Encouraged by these preliminary results, Inhibrx has initiated a new expansion cohort to validate these findings in a more uniform patient population. The cohort is expected to enroll up to 50 patients, each with two to three prior lines of systemic therapy, and data are anticipated in Q3 2025.

"We believe these interim results underscore the potential of ozekibart to provide meaningful clinical benefit for patients with advanced solid tumors, even in heavily pretreated populations. We are particularly encouraged by the durable disease control observed and look forward to further evaluating these findings in our expansion cohort," commented Josep Garcia, Chief Clinical Development Officer at Inhibrx.

About Colorectal Adenocarcinoma

Colorectal adenocarcinoma is the third most frequent cancer globally and the second leading cause of cancer-related death. According to the WHO, there were nearly 2,000,000 new cases of CRC in 2020, with nearly 1,000,000 deaths. Effective therapies beyond the second-line setting are limited. In the U.S., the five-year relative survival rate in patients with metastatic CRC is 15.7%, underscoring the need for better treatments.

About ozekibart (INBRX-109)

Ozekibart is a precision-engineered, tetravalent death receptor 5 (DR5) agonist antibody designed to exploit the tumor-biased cell death induced by DR5 activation.
In January 2021, the FDA granted Fast Track designation to ozekibart for the treatment of patients with metastatic or unresectable conventional chondrosarcoma, and, in November 2021, the FDA granted orphan drug designation to ozekibart for chondrosarcoma.

In June 2021, Inhibrx initiated a randomized, blinded, placebo-controlled, registration-enabling Phase 2 trial of ozekibart in metastatic, unresectable conventional chondrosarcoma, which is currently ongoing and expected to read out in the middle of this year. Additionally, in a Phase 1 trial, Inhibrx is investigating ozekibart in Ewing sarcoma in combination with irinotecan/temozolomide.

About Inhibrx Biosciences, Inc.

Inhibrx Biosciences is a clinical-stage biopharmaceutical company focused on developing a broad pipeline of novel biologic therapeutic candidates. Inhibrx Biosciences utilizes diverse methods of protein engineering to address the specific requirements of complex target and disease biology, including its proprietary protein engineering platforms. Inhibrx Biosciences was incorporated in January 2024 as a direct, wholly-owned subsidiary of Inhibrx, Inc. Prior to the sale of Inhibrx, Inc. and the INBRX-101 program to Sanofi S.A., Inhibrx Biosciences acquired certain corporate infrastructure and other assets and liabilities through a series of internal restructuring transactions effected by Inhibrx, Inc. Inhibrx, Inc. also completed a distribution to holders of its shares of common stock of 92% of the issued and outstanding shares of Inhibrx Biosciences. Following such transactions, Inhibrx Biosciences' current clinical pipeline of therapeutic candidates includes ozekibart (INBRX-109) and

INBRX-106, both of which utilize multivalent formats where the precise valency can be optimized in a target-centric way to mediate what we believe to be the most appropriate agonist function. Both programs have key data readouts expected in 2025. 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 judgments and beliefs regarding the strength of Inhibrx's pipeline any future potential safety and efficacy of its therapeutic candidate, ozekibart; the clinical development of ozekibart, including expected enrollment in the expansion cohort and data readouts and the timing thereof; the potential demand for ozekibart and any presumption that preliminary data will be representative of final data or data in 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; results from preclinical studies or early clinical trials not necessarily being predictive of future results; unexpected adverse side effects or inadequate efficacy of its therapeutic candidates that may limit their development, regulatory approval and/or commercialization; the potential for its programs and prospects to be negatively impacted by developments relating to its competitors, including the results of studies or regulatory determinations relating to its competitors; the timing or likelihood of regulatory filings and approvals and regulatory developments in the U.S. and foreign countries; the successful commercialization of its therapeutic candidates, if approved; an accelerated development or approval pathway may not be available for ozekibart or other therapeutic candidates and any such pathway may not lead to a faster development process; it may not realize the benefits associated with orphan drug designation, including that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained; 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; and other risks described from time to time in the "Risk Factors" section of its filings with the U.S. Securities and Exchange Commission, including those described in its Registration Statement on Form 10, as amended (File No. 001-42031), its Registration Statement on Form S-1, as amended and supplemented from time to time (File No. 333-280127), and its Quarterly Reports on Form 10-Q, and supplemented from time to time by its Current Reports on Form 8-K as filed from time to time. 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.

Investor and Media Contact:

Kelly Deck, CFO
ir@inhibrx.com
858-795-4260

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