Inhibrx Announces U.S. FDA Acceptance of BLA for Ozekibart in Patients with Conventional Chondrosarcoma

- ***No filing review issues identified by FDA with PDUFA goal date set for April 14, 2027***
- ***If Approved, Ozekibart Would Be the First and Only FDA-Approved Treatment for Unresectable or Metastatic Conventional Chondrosarcoma***

SAN DIEGO, June 15, 2026 /PRNewswire/ -- Inhibrx Biosciences, Inc. (Nasdaq: INBX) ("Inhibrx" or the "Company"), a clinical-stage biopharmaceutical company focused on developing novel biologic therapeutic candidates, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its Biologics License Application (BLA) seeking approval of ozekibart (INBRX-109) for the treatment of patients with unresectable or metastatic conventional chondrosarcoma. The FDA has not identified any filing review issues at this time and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of April 14, 2027. "The FDA's acceptance of our BLA for ozekibart is a monumental milestone for Inhibrx and, more importantly, for the chondrosarcoma community," said Mark Lappe, Chief Executive Officer of Inhibrx. "Chondrosarcoma is an aggressive and devastating bone cancer and there are currently no approved therapies for patients suffering from this disease. We look forward to working closely with the FDA during this review process to potentially bring this first-in-class targeted therapy to patients as quickly as possible."

The BLA is supported by positive results from the ChonDRAgon study, a randomized, blinded, placebo-controlled, registrational trial of ozekibart in patients with metastatic or unresectable conventional chondrosarcoma, which met its primary endpoint of a statistically significant and clinically meaningful median progression-free survival (PFS) for patients treated with ozekibart compared to placebo. Ozekibart achieved a 52% reduction in the risk of disease progression or death compared to placebo (stratified Hazard Ratio [HR] 0.479; 95% CI: 0.33, 0.68; P<0.0001), more than doubling median PFS to 5.52 months versus 2.66 months for placebo. Importantly, ozekibart is the first investigational therapy to demonstrate a significant PFS benefit in a blinded, randomized trial for chondrosarcoma, a disease with no approved systemic options.

If approved, ozekibart would become the first commercial product for Inhibrx and the first-ever approved systemic therapeutic for patients with unresectable or metastatic conventional chondrosarcoma.

About Chondrosarcoma
Chondrosarcoma is a rare type of cancer that primarily develops in the cartilage cells of bones, most commonly affecting the pelvis, hip, and shoulder. It stands as the second most common primary bone malignancy. When the disease becomes unresectable or metastatic, the prognosis is historically poor because the tumors are largely unresponsive to traditional oncology treatments, leaving surgical resection as the only effective management strategy for localized disease.

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 the ChonDRAgon study, a randomized, blinded, placebo-controlled, registrational trial of ozekibart in metastatic, unresectable conventional chondrosarcoma. The trial enrolled a total of 206 patients across 67 different sites worldwide. The primary objective of the trial was the evaluation of the efficacy of ozekibart as measured by median PFS, assessed by central real-time independent radiology review per RECIST 1.1. Secondary objectives were the evaluation of overall survival, median PFS by investigator assessment, quality of life, objective response rate, duration of response, disease control rate, safety and tolerability, pharmacokinetics and anti-drug antibodies to ozekibart.

Key enrollment criteria in order for patients to qualify for inclusion in the trial were grade 2 or 3 unresectable or metastatic conventional chondrosarcoma. Patients received either ozekibart or placebo every three weeks at a randomization of 2:1, stratified by the line of therapy, grade and IDH1/2 mutation status.

Patients randomized to the placebo arm were allowed to crossover to receive ozekibart upon confirmation of progression as reported by central independent radiology review.

The ChonDRAgon study met its primary endpoint of a statistically significant and clinically meaningful median progression-free survival (PFS) for patients with advanced or metastatic chondrosarcoma treated with ozekibart compared to placebo. Ozekibart achieved a 52% reduction in the risk of disease progression or death compared to placebo (stratified Hazard Ratio [HR] 0.479; 95% CI: 0.33, 0.68); P<0.0001), more than doubling median PFS to 5.52 months versus 2.66 months for placebo. Importantly,

ozekibart is the first investigational therapy to demonstrate a significant PFS benefit in a randomized trial for chondrosarcoma, a disease with no approved systemic options.

The benefit of ozekibart was consistent across all pre-specified subgroups, including patients with IDH-wild-type and IDH-mutant tumors. Other key secondary endpoints, including disease control rate (54% vs 27.5%), and delay to deterioration in pain and physical function, further supported the clinical benefit observed with ozekibart.

Ozekibart was generally well tolerated, with a manageable safety profile. The most common treatment-related adverse events were fatigue, constipation, and nausea. Hepatotoxicity, a known risk for this mechanism of action, occurs during the first treatment cycle and is in patients with underlying hepatic impairment. One hepatotoxicity-related fatal event occurred early in the study, prior to the implementation of mitigation measures. Over the course of the ChonDRAgon study, this risk was effectively mitigated by excluding patients with severe liver impairment and by implementing close monitoring during early treatment cycles, allowing for prompt management of liver enzyme elevations. This approach resulted in a low overall incidence of treatment-related hepatic adverse events, 11.8% compared to 4.5% in the placebo arm, the majority of which were Grade 1 or 2 in severity.

In addition to the registrational trial in chondrosarcoma, Inhibrx is advancing ongoing expansion cohorts, evaluating ozekibart in combination with irinotecan-based regimens in Ewing sarcoma and colorectal cancer. Encouraging early signals support further exploration of ozekibart's potential in these difficult-to-treat tumor types with high unmet medical need.

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 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. 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; statements regarding the safety and efficacy of its therapeutic candidate, ozekibart, based on topline and interim results; the potential for ozekibart to be used for the treatment of colorectal cancer, Ewing sarcoma and solid tumor indications; the clinical development of ozekibart, including expected enrollment in the expansion cohort, data readouts, regulatory submissions and interactions, and the timing thereof; the potential commercial development of ozekibart, including becoming the first commercial product for Inhibrx; ozekibart becoming the first-ever FDA approved systemic therapeutic for patients with unresectable or metastatic conventional chondrosarcoma; and any presumption that topline, interim or 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: topline data may not accurately reflect the complete results of a particular study or trial and remain subject to audit, and final data may differ materially from topline data; 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 topline, 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 Annual Report on Form 10-K, 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.

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