

Inhibrx Biosciences Reports Positive Topline Results from its Registrational Trial of Ozekibart (INBRX-109) in Chondrosarcoma and Provides Updates on Colorectal Cancer and Ewing Sarcoma Expansion Cohorts

- **Ozekibart meets its primary endpoint in chondrosarcoma**, demonstrating a statistically significant and clinically meaningful improvement in median progression-free survival compared to placebo
- **Key secondary endpoints reinforce the primary benefit**, demonstrating meaningful improvements in disease control and patient quality of life
- **Inhibrx plans to file a BLA** in Q2 of 2026
- **Interim data from expansion cohorts in patients with colorectal cancer and Ewing sarcoma** demonstrate high response and disease control rates in difficult-to-treat, heavily pretreated patients
- **Management to host conference call today at 1:30 p.m. Pacific Time**, to review the topline results and ongoing cohorts

SAN DIEGO, Oct. 23, 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 positive topline results from the registrational ChonDRAGON study (n= 206) investigating ozekibart (INBRX-109) as a single agent versus placebo in patients with advanced or metastatic, unresectable chondrosarcoma. The Company also provided updates on the ongoing expansion cohorts investigating ozekibart in combination with FOLFIRI in late-line colorectal cancer and in combination with irinotecan and temozolomide in refractory Ewing sarcoma.

Chondrosarcoma

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.

"I am very encouraged and enthusiastic about ozekibart and the impact I have seen on my sarcoma patients," said Dr. Robin Jones, head of the sarcoma unit at The Royal Marsden Hospital in London, United Kingdom. "With no approved treatments available, we have observed that ozekibart helps to keep the cancer from growing, improves how patients feel, and restores a sense of hope for my patients."

Detailed results from this trial will be presented at the Connective Tissue Oncology Society (CTOS) Annual Meeting on November 14, 2025.

Colorectal Cancer

Based on initial results from the Phase 1 trial of ozekibart in combination with FOLFIRI for the treatment of advanced or metastatic, unresectable colorectal cancer (CRC), Inhibrx initiated an expansion cohort enrolling 44 patients, as a fourth line of therapy for approximately 70% of patients and as a third line of therapy for approximately 30% of patients. 80% of patients had been previously treated with regimens containing irinotecan. Efficacy, based on RECIST v1.1 criteria, was assessed in 26 evaluable patients to date who had at least one post-baseline scan. The results show a 23% overall response rate (ORR) and

an overall disease control rate of 92%. These outcomes are highly encouraging in a heavily pretreated CRC population, where responses are rare (5-6%) and outcomes are generally poor with the current standard of care.

Ozekibart, in combination with FOLFIRI, was well tolerated. The most common treatment-emergent adverse events included anemia, diarrhea, nausea, and fatigue, with the majority being low-grade and consistent with the known safety profile of FOLFIRI.

Ewing Sarcoma

Based on initial results from the Phase 1 trial of ozekibart in combination with irinotecan and temozolomide (IRI/TMZ) for advanced or metastatic, unresectable, relapsed, or refractory Ewing sarcoma, Inhibrx initiated an expansion cohort which is expected to enroll up to 50 patients. Of the 33 patients recruited to date, more than half were third or fourth line patients. Among the 25 evaluable patients to date, Inhibrx observed a 64% overall response rate (ORR), and a disease control rate of 92%, with the majority of patients experiencing measurable tumor reduction. These outcomes are highly encouraging in this difficult-to-treat patient population as compared to the response rate typically observed with standard IRI/TMZ (15-30%).

Overall, ozekibart in combination with IRI/TMZ was well tolerated. The most common adverse events were diarrhea, nausea, anemia, and fatigue, all consistent with the known safety profile of IRI/TMZ.

"We are excited by these results which suggest the potential of ozekibart to expand not only in sarcomas but also in high unmet need solid tumor indications," said Mark Lappe, CEO and Co-Founder of Inhibrx. "We look forward to working with the FDA to deliver ozekibart to patients as swiftly as possible."

The Company will host a live webcast presentation today, October 23rd, 2025, at 1:30 p.m. Pacific Time to further discuss the results.

About the Conference Call

Investors may join via the web: <https://app.webinar.net/RdZmlEPaEyw> or may listen to the call by dialing (1-888-880-3330). Please refer to Inhibrx Biosciences, Inc. or the conference ID 9577647 when calling in. Following the webcast, the presentation may be accessed through a link on the investors section of Inhibrx's website at <https://inhibrx.com/inhibrx-biosciences-inc-investors/events-and-presentations>. The webcast will be available for 60 days following the event. Following the presentation, Inhibrx will update its corporate presentation within the "Investors" section of its website at www.inhibrx.com.

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, 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.

In addition to the registrational trial, 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 CRC, 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; 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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SOURCE Inhibrx Biosciences, Inc.

<https://inhibrx.investorroom.com/2025-10-23-Inhibrx-Biosciences-Reports-Positive-Topline-Results-from-its-Registrational-Trial-of-Ozekibart-INBRX-109-in-Chondrosarcoma-and-Provides-Updates-on-Colorectal-Cancer-and-Ewing-Sarcoma-Expansion-Cohorts>