Inhibrx Biosciences Provides Progress Updates on the INBRX-106 Program and the Expansion Cohorts of the ozekibart (INBRX-109) Program

SAN DIEGO, Dec. 16, 2025 /PRNewswire/ -- Inhibrx Biosciences, Inc. (Nasdaq: INBX) ("Inhibrx" or the "Company"), a clinical-stage biopharmaceutical company focused on developing therapeutics for oncology today announced an update on the INBRX-106 Phase 2/3 clinical trial in combination with Keytruda® (pembrolizumab) as a first-line treatment for patients with locally advanced unresectable or metastatic head and neck squamous cell carcinoma (HNSCC) and the Phase 1/2 trial evaluating patients with checkpoint inhibitor refractory or relapsed non-small cell lung cancer (NSCLC) in combination with Keytruda. The Company also provided a brief progress update on the expansion cohorts investigating ozekibart in combination with FOLFIRI in late-line colorectal cancer and in combination with irinotecan and temozolomide in refractory Ewing sarcoma.

INBRX-106

Inhibrx has recruited 46 of the 60 patients in the randomized Phase 2 portion of the Phase 2/3 clinical trial evaluating INBRX-106 in combination with Keytruda versus Keytruda as a first-line treatment for patients with unresectable or metastatic HNSCC. Inhibrx expects to complete enrollment in the Phase 2 portion of the trial during the first quarter of 2026. This trial is recruiting patients who have not received prior systemic therapy for unresectable or metastatic HNSCC and have tumor PD-L1 CPS expression equal to or greater than 20. Patients are randomized one to one to either INBRX-106 in combination with Keytruda or Keytruda. The primary endpoint of the Phase 2 portion of this trial is overall response rate, supported by secondary endpoints of duration of response, progression free survival and safety.

In November 2025, Inhibrx completed enrollment of the Phase 1/2 trial evaluating 34 patients in checkpoint inhibitor refractory or relapsed NSCLC in combination with Keytruda. Primary endpoints for this cohort are objective response rate, disease control rate, duration of response and safety.

The current datasets for both HNSCC and NSCLC lack sufficient maturity to support an interpretation and conclusion on the viability of this program. Inhibrx expects that in the second half of 2026, the data should be mature enough to inform whether INBRX-106, in combination with Keytruda, demonstrates superior efficacy and sustained clinical benefit relative to the current standard of care.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp.

Ozekibart (INBRX-109)

In late October 2025, Inhibrx completed enrollment of 44 patients in the expansion cohort of the Phase 1/2 trial evaluating ozekibart in combination with FOLFIRI in heavily pretreated (third and fourth line) advanced or metastatic, unresectable colorectal cancer. As previously reported, ozekibart in combination with FOLFIRI was well tolerated, with durable responses and a high rate of disease control. The progression free survival data should be mature in the second quarter of 2026, and we plan to provide an update at that time.

Inhibrx expects to complete enrollment in the Phase 1/2 trial of ozekibart in combination with irinotecan and temozolomide (IRI/TMZ) for advanced or metastatic, unresectable, relapsed, or refractory Ewing sarcoma in the second quarter of 2026. If the current response and duration trends observed continue, Inhibrx plans to meet with the FDA in the second half of 2026 to discuss an accelerated approval pathway for this indication.

About INBRX-106

INBRX-106 is a precisely engineered hexavalent sdAb-based therapeutic candidate targeting OX40, designed to be an optimized agonist of this co-stimulatory receptor. It is currently being investigated in combination with Keytruda in patients with locally advanced or metastatic solid tumors, specifically HNSCC and NSCLC.

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. Inhibrx read out a successful single agent registration study in chondrosarcoma and a BLA filing is expected in early Q2 of 2026. Additionally, Inhibrx is evaluating ozekibart in patients diagnosed with colorectal cancer and Ewing sarcoma.

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 candidatesbased on topline and interim results; the potential for its therapeutic candidates to be used for certain indications; the clinical development of its therapeutic candidates, including expected enrollment, 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 its 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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