Inhibrx Reports Interim Phase 2 Data for INBRX-106 in First-Line HNSCC; Initial Results Demonstrate Potential Costimulatory Benefit Over PD-1 Monotherapy

- **Interim analyses show INBRX-106 + pembrolizumab achieved a 44.0% confirmed Objective Response Rate (cORR):** In the preliminary confirmed response-evaluable population, the INBRX-106 + pembrolizumab combination achieved a cORR of 44.0% versus 21.4% with pembrolizumab alone, representing a 22.6% absolute increase in cORR.
- **Superior depth of response:** Responding patients in the combination arm demonstrated deeper tumor reductions overall, with the majority achieving target lesion shrinkage exceeding 50%; notably, three patients achieved a complete radiographic response.
- **Up to 15-fold mean increase in systemic T-Cell expansion:**Peripheral blood analysis showed robust CD8+ and CD4+ T-cell proliferation in combination-treated patients, providing mechanistic support for the observed clinical activity.
- **Manageable safety profile:** The combination demonstrated a manageable preliminary safety profile consistent with that expected from an immunotherapy combination.

SAN DIEGO, May 11, 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 positive interim results from the randomized, first-line Phase 2 portion of the HexAgon study. The trial evaluated the safety and efficacy of INBRX-106, a hexavalent OX40 agonist, in combination with pembrolizumab (the combination arm) versus pembrolizumab monotherapy (the control arm) in first-line patients with treatment-naïve, PD-L1 positive (CPS ≥ 20) metastatic or unresectable recurrent Head and Neck Squamous Cell Carcinoma (HNSCC).

HNSCC was selected as a proof-of-concept indication, as PD-1 monotherapy is active in this tumor type but leaves significant room for improvement. The trial design was modeled after KEYNOTE-048, focusing on patients with high PD-L1 expression (CPS ≥ 20) in order to further sharpen the ability to detect a treatment effect above checkpoint inhibition alone. A clear signal of added benefit in this study design would support INBRX-106's potential to enhance checkpoint inhibitor efficacy across checkpoint inhibitor-sensitive indications.

The Phase 2 portion of the HexAgon study enrolled 68 patients: 33 randomized to the combination arm and 35 to the control arm. Baseline prognostic factors are largely balanced between both arms and the study is being conducted at over 80 sites in the United States, Europe and Asia. Today, the Company presented preliminary data from 53 patients (25 in the INBRX-106 combination arm and 28 in the control arm) with a data cutoff of May 7, 2026, representing the evaluable population for confirmed response, defined as patients who had either experienced confirmed disease progression or death, or completed at least two on-study tumor assessments. The remaining 15 patients in the overall population across both arms had not yet reached the maturity threshold for response confirmation or were not evaluable at the time of this data cut and were therefore not included in this analysis. Active unconfirmed responses and ongoing tumor increases/reductions are present in both arms, and these patients are expected to contribute to the final efficacy dataset in a subsequent update.

In the evaluable population, 11 out of 25 patients (44.0%) in the INBRX-106 combination arm achieved a confirmed objective response, compared with 6 out of 28 patients (21.4%) in the control arm. This represents a 22.6% absolute increase in confirmed responses. Three complete responses were observed in the INBRX-106 combination arm, reflecting tumor clearance, while no complete responses were observed with pembrolizumab alone. Complete responses in first-line HNSCC remain uncommon and are generally associated with more durable outcomes.

These clinical findings were supported by pharmacodynamic data, which showed up to a 15-fold increase in peripheral CD8+ and CD4+ T-cell proliferation and up to a four-fold increase in activation in INBRX-106 combination-treated patients compared with up to 2.5-fold and 1.5-fold increases, respectively, in those receiving pembrolizumab alone. The observation of robust systemic T-cell expansion and activation in combination-treated patients, alongside the clinical activity observed in this arm, is consistent with the expected mechanism of action of INBRX-106 as a potent T-cell costimulator.

The combination of INBRX-106 and pembrolizumab was generally manageable, with a safety profile consistent with the addition of an active immunostimulatory agent to checkpoint blockade. The most common treatment-related adverse events were rash, diarrhea, fatigue, and infusion-related reactions, which were predominantly low-grade. No treatment-related deaths were reported in either arm.

"We are greatly encouraged by these early clinical results," said Mark Lappe, Chief Executive Officer of Inhibrx. "These data, coupled with the clear evidence of T-cell expansion and superior depth of response, give us confidence that INBRX-106 could be the first costimulatory agent to fundamentally shift the efficacy ceiling of immunotherapy, and open the door to combinations with new modalities that could be enhanced by OX40 agonism."

Next Steps

The progression-free survival data from the Phase 2 portion of the HexAgon study are expected to become available in the fourth quarter of 2026. The Company plans to begin the Phase 3 portion of the HexAgon study during the third quarter of 2026.

Based on these promising early results, the Company also aims to evaluate INBRX-106 across broader indications to potentially improve the efficacy of checkpoint inhibitors. This strategy includes initiating a study in the perioperative setting in non-small cell lung cancer (NSCLC) later this quarter. The Company believes OX40 agonism has the greatest potential to drive cure in earlier-stage disease settings, where patients typically retain a more active and responsive immune system. In addition, the Company is beginning to plan for expansion into the front-line metastatic NSCLC setting, with studies expected to begin in 2027. Outside of combination with checkpoint inhibitors, the Company plans to explore combinations with agents that could benefit from T-cell costimulation, such as vaccines, T-cell engagers, and CAR-Ts.

About INBRX-106

INBRX-106 is a hexavalent agonist targeting OX40 (CD134), a costimulatory receptor on T-cells. Utilizing Inhibrx's proprietary single-domain antibody (sdAb) platform, INBRX-106 is designed to achieve the high-order receptor clustering necessary for robust T-cell activation and survival, a feat that has eluded traditional bivalent antibody approaches. To date, over 175 patients have been treated with INBRX-106.

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. 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, INBRX-106, based on topline and interim results; the potential for INBRX-106 to be used for the treatment of HNSCC; the clinical development of INBRX-106, including expected enrollment in the expansion cohort, data readouts, regulatory submissions and interactions, and the timing thereof; any presumption that topline, interim or preliminary data will be representative of final data or data in later clinical trials, including data from the remaining 15 patients in the overall population for the Phase 2 trial for INBRX-106 in first-line HNSCC; Inhibrx's plans to evaluate INBRX-106 across broader indications and to explore combinations with other therapies; Inhibrx's plans to expand into the front-line metastatic NSCLC setting, with studies expected to begin in 2027; and Inhibrx's plans to begin the Phase 3 portion of the HexAgon study during the third quarter of 2026. 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; 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.

Investor and Media Contact:
Kelly Deck, CFO
ir@inhibrx.com
858-795-4260

SOURCE Inhibrx Biosciences, Inc.
