Inhibrx Announces Initial Phase 1 Dose Escalation Results for INBRX-106, a Novel Hexavalent OX40 Agonist, in Combination with Keytruda® (Pembrolizumab) Along with Updated Single Agent Data

- Two durable partial responses in checkpoint inhibitor-naive nasopharyngeal carcinoma and uveal melanoma patients in dose escalation of INBRX-106 in combination with Keytruda®
- Durable single agent-driven disease control observed in NSCLC and melanoma patients with prior checkpoint inhibitor exposure
- Part 4 (combination dose expansion) cohorts of INBRX-106 in combination with Keytruda® initiated in checkpoint therapy failure and checkpoint inhibitor naïve patients with initial data expected later this year

SAN DIEGO, Jan. 4, 2022 /PRNewswire/ -- Inhibrx, Inc. (Nasdaq: INBX), a biotechnology company with four clinical programs in development and a strong emerging pipeline, today announced initial results from Part 3 (combination dose escalation) of the 4-part Phase 1 trial of INBRX-106, a novel hexavalent OX40 agonist, in combination with Keytruda®, in development for the treatment of patients with solid tumors. Additionally, an update on single agent data from Part 1 (single agent dose escalation) and Part 2 (single agent dose expansion) of the trial was provided.

In the all-comer Part 3 of this Phase 1 trial, the dose of INBRX-106 was escalated in combination with Keytruda® in 21 patients with locally advanced or metastatic solid tumors. INBRX-106 in combination with Keytruda® was observed to be well tolerated, with predominantly mild or moderate immune-related toxicities noted. The maximum administered dose of INBRX-106 was 0.3 mg/kg, at which dose-limiting, immune-related toxicities such as dermatitis were observed. Accordingly, 0.1 mg/kg dosed every three weeks was determined to be the maximum tolerated dose (MTD) of INBRX-106 in combination with Keytruda®.

Out of five response evaluable patients with tumor types responsive to immunotherapy in the active dose range of INBRX-106 in combination with Keytruda, two durable partial responses were achieved in checkpoint inhibitor naïve nasopharyngeal carcinoma and uveal melanoma patients with duration greater than six months with treatment ongoing. Additionally, a third checkpoint inhibitor exposed cutaneous melanoma patient has a double-digit reduction in tumor volume and duration greater than four months with treatment ongoing.

Part 2, which was run in parallel with Part 3, is ongoing and aimed at investigating single agent INBRX-106 dosed at 0.03 mg/kg in two different dosing schedules in patients with tumor types responsive to checkpoint inhibitors. Four of ten response evaluable non-small cell lung cancer (NSCLC) and melanoma patients receiving INBRX-106 in either Part 1 or 2 of the trial have been on treatment with INBRX-106 for at least six months. Of those four patients, three had previous exposure to checkpoint inhibitors and the fourth, a uveal melanoma patient, was checkpoint inhibitor naïve. To date, the longest duration on treatment with single agent INBRX-106 is 90 weeks (approximately 21 months) and ongoing in a NSCLC patient refractory to Keytruda®.

"We believe the early activity of single agent INBRX-106 and INBRX-106 in combination with Keytruda® observed in patients who relapsed or are refractory to checkpoint inhibitors as well as in patients with tumor types responsive to immunotherapy that respond poorly to checkpoint inhibitors is very encouraging" said Mark Lappe, CEO of Inhibrx. "We are pleased to see that our preclinical data, which demonstrated that hexavalent valency is required to properly agonize OX40, appear to be translating clinically."

Part 4 (combination dose expansion) of the trial initiated in a NSCLC cohort and a basket cohort in patients who relapsed or were refractory to checkpoint inhibitors, as well as in selected checkpoint inhibitor naive patient cohorts including cutaneous melanoma, uveal melanoma, head and neck squamous cell carcinoma and nasopharyngeal carcinoma. We expect to have initial data from Part 4 of this trial late this year.

About INBRX-106
INBRX-106 is a hexavalent product candidate agonist of OX40. OX40 is a co-stimulatory receptor expressed on immune cells that is enriched in the tumor microenvironment. OX40 ligand is a trimeric protein that activates OX40 signaling through clustering. We engineered INBRX-106 to bind and cluster six OX40 receptors and has been shown preclinically to significantly outperform bivalent antibodies in co-stimulatory capacity and anti-tumor activity.

The trial for INBRX-106 is a first-in-human, multicenter, open-label, non-randomized, 4-part Phase 1 trial in patients with locally advanced or metastatic solid tumors designed to determine the safety profile and identify the MTD and/or recommended Phase 2 dose of INBRX-106 administered as a single agent or in combination with Keytruda® (pembrolizumab), a programmed death receptor-1 (PD-1) checkpoint inhibitor.

About the Inhibrx sdAb Platform
Inhibrx utilizes diverse methods of protein engineering in the construction of therapeutic candidates that can address the specific requirements of complex target and disease biology. A key tool for this effort is the Inhibrx proprietary sdAb platform, which enables the development of therapeutic candidates with attributes superior to other monoclonal antibody and fusion protein approaches. This platform allows the combination of multiple binding units in a single molecule, enabling the creation of therapeutic candidates with defined valency or multiple specificities, potentially capable of enhanced cell signaling or conditional activation. An additional benefit of this platform, these optimized and/or multi-functional entities can be manufactured using the established processes that are commonly used to produce therapeutic proteins.

Inhibrx is pursuing targets with early validation where other therapeutics have demonstrated liabilities as well as a portfolio of sdAb based therapeutic candidates in a variety of indications for novel targets.

About Inhibrx, Inc.
Inhibrx is a clinical-stage biotechnology company focused on developing a broad pipeline of novel biologic therapeutic candidates in oncology and orphan diseases. Inhibrx utilizes diverse methods of protein engineering to address the specific requirements of complex target and disease biology, including its proprietary sdAb platform. Inhibrx has collaborations with 2seventy bio (formerly bluebird bio), Bristol-Myers Squibb and Chiesi. 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 and its investigators' judgments and beliefs regarding the strength of Inhibrx's pipeline, any future potential or observed to date safety and efficacy of its therapeutic candidate, INBRX-106, the clinical translatability of any observed preclinical data and statements and beliefs regarding the clinical development of INBRX-106 and any presumption of positive results from Phase 1 clinical trials, including any implied or presumed positive results, disease control or efficacy based on initial data observed to date. 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; the timing or likelihood of regulatory filings and approvals; 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; the implementation of its business model and strategic plans for its business and therapeutic candidates; its ability to successfully manufacture therapeutic candidates for clinical trials and commercial use, if approved; its ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; its ability to obtain any needed clinical trial supplies from third-party suppliers; the scope of protection it is able to establish and maintain for intellectual property rights covering its therapeutic candidates; its ability to enter into strategic partnerships and the potential benefits of these partnerships; its estimates regarding expenses, capital requirements and needs for additional financing and financial performance; its expectations regarding the impact of the COVID-19 pandemic on its business; and other risks described from time to time in the "Risk Factors" section of its filings with the U.S. Securities and Exchange Commission, or the SEC, including those described in its Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the SEC on March 12, 2021, as well as its Quarterly Reports on Form 10-Q, and supplemented from time to time by its Current Reports on Form 8-K. 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. This press release contains estimates and other statistical data made by independent parties and by Inhibrx. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. The statements in this press release are solely those of Inhibrx and its management and do not represent the views of any third party. The mark "Inhibrx" is Inhibrx's registered trademark. All other service marks, trademarks and trade names appearing in this release are the property of their respective owners. Inhibrx does not intend its use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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