# Inhibrx Announces Phase 1 Dose Escalation Results of INBRX-106, a Novel Hexavalent OX40 Agonist

SAN DIEGO, Jan. 5, 2021 /PRNewswire/ -- Inhibrx, Inc. (Inhibrx), a clinical-stage biotechnology company with a broad pipeline of biotherapeutics in development, announced today results from Part 1 of the Phase 1 dose escalation trial of INBRX-106, a novel hexavalent OX40 agonist, in development for the treatment of solid tumors.

The trial 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 maximum tolerated dose (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.

The single-agent dose escalation part of this Phase 1 trial enrolled 20 patients. In this Phase 1 trial, INBRX-106 was observed to be well tolerated, with mostly mild or moderate immune-related toxicities noted, in line with the mechanism of action of this candidate therapeutic. The maximum administered dose was 3 mg/kg and the MTD level was not reached. Signs of clinical benefit to date were observed in patients with a range of tumor types, including those generally considered to be hot and cold, as well as in individuals that were relapsed or refractory to checkpoint inhibitors. Activity was observed at dose levels in a range from 0.0003 to 0.3 mg/kg and peripheral biomarker sampling confirmed agonist activity across these low doses. With the conclusion of Part 1 (the single agent dose escalation), Part 2 (single-agent expansion) and Part 3 (combination dose escalation) of the trial will both be initiated this month.

In the Part 2 expansion cohort, the 0.03 mg/kg dose level administered in various dosing schedules will be investigated in patients with tumor types generally responsive to checkpoint inhibitors. Key attributes leading to the choice of this dose level include rapid loss of OX40 after dosing, evidence of peripheral memory T cell activation and proliferation, and sufficient drug clearance to allow target recovery prior to the next dose administration.

In the Part 3 combination dose escalation cohort, INBRX-106 will be evaluated in combination with Keytruda . Preclinical data suggests INBRX-106 may have improved anti-tumor activity with concurrent blockade of the PD-1 checkpoint. Efficacy and safety data from the combination escalation cohort are expected to be reported in the second half of 2021, at which time and assuming positive results, Part 4, the combination expansion cohort, will begin in NSCLC and other tumor types generally responsive to checkpoint inhibitors.

"We believe the early activity of single agent INBRX-106 that we observed at low doses is encouraging and aligns with our preclinical data, which described a bell-shaped dose response curve and potent OX40 agonist activity," said Mark Lappe, CEO of Inhibrx. "We are excited to move into the combination phase of the trial to evaluate if the addition of Keytruda will accentuate the anti-tumor activity of INBRX-106 and potentially expand the patient population responsive to checkpoint inhibition."

**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.  INBRX-106 was engineered 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.

**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, multi-functional entities can be manufactured using the established processes that are commonly used to produce therapeutic proteins.

Initially, Inhibrx is pursuing targets with early clinical validation, such as OX40, where other therapeutics have demonstrated liabilities. In addition, Inhibrx is developing a portfolio of sdAb based therapeutic candidates in a variety of indications for both known and novel targets.

**About Inhibrx Inc.**

Inhibrx is a clinical-stage biotechnology company focused on developing a broad pipeline of biologic therapeutic candidates. Inhibrx utilizes diverse methods of protein engineering to therapeutically address the specific requirements of complex target and disease biology, including its proprietary sdAb platform. The Inhibrx pipeline is currently focused on oncology and orphan diseases. Inhibrx has collaborations with bluebird bio, Celgene 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 observed safety and efficacy to date of its therapeutic candidates in clinical trials, data observed in its preclinical studies and beliefs regarding the future clinical development of INBRX-106. 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; 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 in Inhibrx's filings with the U.S. Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in Inhibrx's Form 10-Q for the quarter ended September 30, 2020 filed with the SEC on November 13, 2020 and any subsequent filings with the SEC. 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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