Instil Bio Announces Voluntary Pause of Enrollment in Ongoing Clinical Trials Related to Manufacturing

October 31, 2022

- *Voluntarily paused enrollment in ITIL-168 and ITIL-306 trials pending outcome of manufacturing analysis and implementation of corrective actions*
- *No regulatory agency, including the FDA, has notified the Company of a clinical hold in any of its clinical trials*
- *Observed decreased rate of successful manufacturing of ITIL-168 for patients recently enrolled in DELTA-1 trial*
- *Company intends to provide an update on the manufacturing analysis by early Q1 2023*
- *Company confirms cash runway into 2025 upon the successful completion of a potential sale-leaseback transaction of its Tarzana manufacturing facility*

DALLAS, Oct. 31, 2022 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil”) (Nasdaq: TIL), a clinical-stage biopharmaceutical company focused on developing tumor infiltrating lymphocyte, or TIL, therapies for the treatment of patients with cancer, today announced that it has voluntarily paused enrollment in its ongoing clinical trials of ITIL-168 and ITIL-306 and has notified regulatory authorities in the United States, Canada, and the UK. No regulatory agencies, including the FDA, have notified the Company of a clinical hold in any of its clinical trials.

The voluntary pause by the Company was instituted following a recent decrease in the rate of successful manufacturing of ITIL-168, resulting in the inability to dose some patients whose individual product of ITIL-168 was not successfully manufactured. A pre-specified safety analysis in the DELTA-1 trial has been conducted on patients who received ITIL-168 and did not identify any unexpected safety issues. The Company has commenced an end-to-end analysis of its manufacturing processes and upon completion of this analysis, plans to take corrective actions to improve the rate of manufacturing success and resume the study. Although no manufacturing failures have been observed to date in the ongoing Phase 1 trial of ITIL-306, the Company has also voluntarily paused enrollment in this trial as part of its overall manufacturing analysis.

“We are committed to advancing TIL therapy for the treatment of patients with cancer,” said Bronson Crouch, Chief Executive Officer of Instil Bio. “This pause in enrollment provides us an opportunity to refine our processes and enable us to manufacture and deliver TIL therapies to patients with no other treatment options. We have assembled a world-class technical operations organization and leadership team to address the challenges associated with manufacturing these therapies.”

“With the quality of our technical operations staff and our significant experience in developing cell therapies, I am confident in our ability to overcome obstacles in manufacturing,” said Tim Moore, Chief Operating Officer of Instil Bio. “Our end-to-end manufacturing analysis is being carried out to expeditiously identify contributing causes, design solutions, and implement corrective actions in order to resume clinical manufacturing.”

The Company intends to provide an update on the manufacturing analysis by early Q1 2023. The Company confirms its previously disclosed cash runway into 2025 upon the successful completion of a potential sale-leaseback transaction of its Tarzana manufacturing facility.

About Instil Bio

Instil Bio, Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing TIL therapies for the treatment of patients with cancer. The Company has assembled an accomplished management team with a successful track record in the development, manufacture, and commercialization of cell therapies. Using the Company’s proprietary, optimized, and scalable manufacturing processes at its in-house manufacturing facilities, Instil is advancing its lead TIL product candidate, ITIL-168, for the treatment of advanced melanoma and other solid tumors as well as ITIL-306, a next-generation, genetically engineered TIL therapy for multiple solid tumors. For more information visit www.instilbio.com and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipates,” “believes,” “expects,” “future,” “intends,” “potential,” “projects,” and “will” or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying our pipeline of potential therapies, the Company’s investigation into its manufacturing processes of ITIL-168, the implementation of corrective actions and resumption of clinical trials, future updates about the Company’s clinical trials, the Company’s cash runway, and other statements that are not historical fact. Forward-looking statements are based on management’s current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements, including risks and uncertainties associated with the costly and time-consuming cell therapy product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating, enrolling, reporting data from or completing clinical studies, as well as the risks that results obtained in clinical trials to date may not be indicative of

results obtained in ongoing or future trials and that Instil's product candidates may otherwise not be effective treatments in their planned indications; the ongoing COVID-19 pandemic, which could materially and adversely affect Instil's business and operations, including Instil's ability to timely initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; risks inherent in manufacturing and testing of cell therapy products and the ability to overcome challenges related thereto; the sufficiency of Instil's cash resources, and other risks and uncertainties affecting Instil and its development programs, including those discussed in the section titled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that we make from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

Contacts:

Media Contact:
1-833-446-7845 Ext. 1009
mediarelations@instilbio.com

Janhavi Mohite
Stern Investor Relations
1-212-362-1200
janhavi.mohite@sternir.com