

# Instil Bio Announces Prioritization of Genetically Engineered CoStAR-TIL Program with ITIL-306 in Advanced Solid Tumors and Reduction in Workforce

December 8, 2022

- Discontinuing unmodified TIL programs, including DELTA-1 and DELTA-2 trials of ITIL-168
- Prioritizing CoStAR-TIL programs for clinical development, including ITIL-306 in Phase 1 trial for NSCLC, ovarian, and renal cell carcinoma
- Reducing U.S. headcount by approximately 60%

DALLAS, Dec. 08, 2022 (GLOBE NEWSWIRE) -- Instil Bio, Inc. ("Instil" or the "Company") (NASDAQ: TIL), a clinical-stage biopharmaceutical company focused on developing next-generation tumor infiltrating lymphocyte, or TIL, therapies for the treatment of patients with cancer, today announced a reprioritization of its clinical programs to focus on development of its CoStAR-TIL product candidates.

"From the beginning of Instil, we have been committed to advancing TIL therapy by enhancing the native activity of TILs with innovative strategies designed to improve product efficacy and safety," said Bronson Crouch, CEO of Instil Bio. "Although it was a difficult decision to discontinue the development of ITIL-168, this decision provides us the opportunity to accelerate the development of CoStAR and other novel technologies to enhance TIL therapies for patients. We are excited to resume dosing patients in the Phase 1 ITIL-306 study and anticipate providing initial data readouts next year."

## Strategic Update

Instil has prioritized development of its proprietary, genetically-engineered CoStAR-TIL programs, which are designed to boost the efficacy of T cells by providing potent synthetic costimulatory signals within the tumor microenvironment (TME). Instil's lead CoStAR-TIL program, ITIL-306, is in a Phase 1 dose escalation trial in non-small cell lung cancer ("NSCLC"), ovarian cancer, and renal cell carcinoma, with the first patient dosed <u>earlier this</u> year. The Company expects to report data from the dose escalation cohorts of the Phase 1 ITIL-306 study in 2023.

Instil is undertaking a reduction in its U.S. workforce of approximately 60% to re-align its operating model from a registration-focused company to a development-stage company.

## **ITIL-168 Program Update**

Instil is discontinuing its ITIL-168 clinical programs, the DELTA-1 trial in advanced melanoma and the DELTA-2 trial in NSCLC, cervical cancer, and head and neck squamous cell carcinoma. After an analysis of the potential scenarios to restart and complete a registration-enabling cohort in advanced melanoma in the DELTA-1 trial, the Company has decided to prioritize the CoStAR-TIL platform.

### About Instil Bio

Instil Bio, Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing next-generation TIL therapies for the treatment of patients with cancer. The Company has assembled an accomplished management team with a successful track record in the research, development, manufacture, and commercialization of cell therapies. Instil is advancing its lead CoStAR-TIL product candidate, 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 and the development thereof, our plans regarding enrollment in our ITIL-306 clinical trial and expectations concerning the availability of initial clinical data from such study and the timing thereof, 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; the sufficiency of Instil's cash resources; our ability to achieve the expected benefits of our corporate reorganization; 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 guarter ended September 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 forwardlooking 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.

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