Instil Bio Presents Clinical Data in Metastatic Melanoma in a Late-Breaking e-Poster at the 2021 American Association for Cancer Research (AACR) Annual Meeting

April 12, 2021

67% overall response rate and 19% complete response rate in 21 patients

All complete responders remained in remission at time of data cut-off

DALLAS, April 12, 2021 (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, presented clinical data from a compassionate use program for the treatment of metastatic melanoma at the American Association for Cancer Research (AACR) virtual meeting April 10 – 15, 2021. The presentation abstract and additional information is available on the AACR conference web site at www.aacr.org.

“Despite the recent advances in immunotherapy for solid tumors, many patients do not receive clinical benefit or experience relapse after an initial remission,” said Robert Hawkins, MBBS FRCP, PhD, Chief Strategy Advisor to Instil and presenting study author. “In this compassionate use setting in which patients had exhausted all other available therapies, a one-time treatment with TILs was able to induce a remission in more than half of the treated patients.”

“This presentation highlights the potential for ITIL-168 to produce deep and durable remissions in patients with advanced melanoma,” said Bronson Crouch, Chief Executive Officer of Instil. “We eagerly anticipate beginning a global Phase 2 clinical trial investigating ITIL-168 for the treatment of advanced melanoma later this year.”

In this compassionate use program, 21 patients with stage IV cutaneous melanoma were treated between 2011 and 2019 at the Christie Hospital in Manchester, United Kingdom with TILs manufactured by Instil. All TIL products were generated in Instil’s company-operated, in-house manufacturing facilities in Manchester.

Among the 21 patients, 14 (67%) achieved an objective response, with four (19%) achieving a complete response. All complete responders remained in remission at the time of data cutoff with those remissions ranging in duration from 30 months to over 80 months from TIL infusion. With a median duration of follow-up of 52.2 months, the median overall survival was 21.3 months with nearly half of patients experiencing long term survival. Side effects of treatment were largely transient, self-limited and generally attributable to the lymphodepleting chemotherapy regimen and post-TIL IL-2 treatment.

The company plans to submit these results for peer-reviewed publication in 2021.

Instil expects to begin a Phase 2 trial of ITIL-168 in advanced melanoma patients in the second half of 2021. The company anticipates obtaining topline safety and efficacy data in 2023, which could support the submission of a BLA to the FDA in 2023 and a Marketing Authorization Application to the European Medicines Agency in 2024.

Poster Information:

Title: Clinical Feasibility and Treatment Outcomes with Unselected Autologous Tumor Infiltrating Lymphocyte Therapy in Patients with Advanced Cutaneous Melanoma

Session Type: E-Poster Session

Session Title: Adoptive Cell Therapy

Abstract Number: LB150

About ITIL-168

ITIL-168 is an investigational, autologous cell therapy made from tumor infiltrating lymphocytes, or TILs. ITIL-168 is manufactured with Instil’s proprietary, optimized, and scalable manufacturing process, which has been designed to capture and preserve the maximum diversity of each patient’s TILs; the manufacturing process also offers significant scheduling flexibility for patients and physicians at the time of both tumor resection and TIL treatment. Instil plans to investigate ITIL-168 in a global phase 2 trial in advanced melanoma in 2021 and additional solid tumor indications in Phase 1 clinical trials beginning in 2022.

About Instil Bio

Instil Bio, Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing tumor infiltrating lymphocyte, or 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," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying the potential of our product candidates to positively impact quality of life and alter the course of disease in the patients we seek to treat, our research, development and regulatory plans for our product candidates, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed and marketed. 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. 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. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings, including in our prospectus dated March 18, 2021, as filed with the SEC on March 22, 2021, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, which is 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. 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

Investor Relations Contact:
1-972-499-3350
investor.relations@instilbio.com
www.instilbio.com

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