Instil Bio Presents Subset Analysis of Patients with Checkpoint-Refractory Advanced Melanoma from Compassionate Use Study at 2021 ESMO Congress

September 16, 2021

DALLAS, Sept. 16, 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, announced today that a subset analysis of treatment outcomes with unselected autologous tumor infiltrating lymphocytes (TILs) in patients with checkpoint inhibitor-refractory advanced cutaneous melanoma was presented today at the 2021 European Society for Medical Oncology (ESMO) Congress, taking place virtually from September 16-21, 2021.

Among the 12 patients featured in this subset analysis who had disease progression following treatment with a PD-1 inhibitor, all were also resistant to CTLA-4 inhibition with ipilimumab. Seven (58%) patients achieved an objective response, with 1 (8%) achieving a complete response. With a median duration of follow-up of 45.5 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, manageable with supportive care, and generally attributable to the lymphodepleting chemotherapy regimen and post-TIL high-dose IL-2 treatment. Outcomes in this highly treatment-refractory subgroup were similar to those observed in all 21 treated patients, with high response rates and an expected safety profile.

“The results of this analysis of a difficult-to-treat subgroup of patients further demonstrate that TIL therapy may offer benefit to patients with advanced melanoma once standard treatments have failed,” said Zachary Roberts, M.D., Ph.D., Chief Medical Officer of Instil Bio. “We eagerly anticipate building on these results in DELTA-1, our Phase 2 study of ITIL-168 in patients with advanced melanoma.”

Poster Presentation Details
Title: Treatment outcomes with unselected autologous tumor infiltrating lymphocytes (TILs) in patients (pts) with checkpoint inhibition–refractory advanced cutaneous melanoma
Poster Session: ePoster Display
Poster Number: 1058P

About ITIL-168

ITIL-168 is an investigational, autologous cell therapy made from tumor infiltrating lymphocytes, or TILs. Made from each patient’s digested and cryopreserved tumor, ITIL-168 is a TIL cell therapy manufactured to offer an unrestricted T cell receptor (TCR) repertoire. Instil’s proprietary, optimized, and scalable manufacturing process has been designed to capture and preserve the maximum diversity of each patient’s TILs. By collecting the patient’s tumor and immediately processing and then cryopreserving it, our process offers significant scheduling flexibility for patients and physicians at the time of both tumor resection and TIL treatment. In addition to DELTA-1, Instil plans to investigate ITIL-168 in additional solid tumor indications in Phase 1 clinical trials beginning in 2022.

About DELTA-1

DELTA-1 is a global, multicenter Phase 2 clinical trial of ITIL-168 in adult patients with advanced melanoma. Using an open-label, single-arm design, the main study cohort will evaluate the efficacy and safety of ITIL-168, when administered after a 5-day course of lymphodepleting chemotherapy and followed by up to 8 doses of high-dose interleukin-2 (IL-2), in patients whose cancer has progressed following a PD-1 inhibitor and, if positive for a BRAF-activating mutation, a BRAF inhibitor. Approximately 80 subjects are planned for enrollment and treatment in Cohort 1. Cohort 2 is anticipated to enroll approximately 25 subjects and is designed to evaluate the efficacy and safety of the regimen in patients who required discontinuation of PD-1 inhibitor(s) due to unacceptable toxicity, regardless of best overall disease response. Cohort 3 is also anticipated to enroll approximately 25 subjects and will evaluate efficacy and safety in patients whose best ongoing response to PD-1 inhibitor(s) is stable disease. Patients in Cohorts 2 and 3 whose cancer expresses a BRAF-activating mutation will be required to have experienced disease progression following BRAF inhibitor therapy. The primary endpoint of DELTA-1 is the objective response rate (ORR) according to RECIST v1.1 as assessed by independent central review. Secondary endpoints include disease control rate, duration of response, progression-free survival, overall survival, and safety.

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, including the design and enrollment of the DELTA-1 clinical trial, the timing of initiating clinical trials, the timing of reporting of data and the timing of regulatory submissions, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, whether, if approved, these product candidates will be successfully distributed and marketed, and our clinical manufacturing capabilities. 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 Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, as filed with the SEC on August 12, 2021, 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.

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