Instil Bio Receives IND Clearance to Initiate a Phase 2 Clinical Trial for Patients with Advanced Melanoma

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Main Study Cohort: *Phase 2 clinical trial with registrational intent for patients with advanced melanoma*

Additional Cohorts*: ITIL-168 clinical trial expanded during IND review process with two additional cohorts, broadening the study target population*

DALLAS, Sept. 13, 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, today reported clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate DELTA-1, a global Phase 2 clinical trial of ITIL-168 in patients with advanced melanoma whose disease has relapsed after a PD-1 inhibitor and, if positive for a BRAF-activating mutation, a BRAF inhibitor.

The DELTA-1 trial was expanded during the IND review process, in consultation with FDA, to include additional populations of patients with advanced melanoma. Cohorts 2 and 3 will enroll patients who discontinued PD-1 inhibitor therapy due to intolerable toxicity and patients who had an unsatisfactory response to prior PD-1 inhibitor but have not yet experienced disease progression, respectively. Topline safety and efficacy results are expected in 2023 and, if positive, are anticipated to support the submission of a biologics license application (BLA) to the FDA in 2023 and a Marketing Authorization Application (MAA) to the European Medicines Agency in 2024.

“The IND clearance for the DELTA-1 Phase 2 clinical trial is a testament to the talent, experience and devotion of the Instil Bio team,” said Bronson Crouch, Chief Executive Officer of Instil. “Motivated by patients in need, our organization will develop ITIL-168 commercially as we expand our clinical programs with current and next-generation therapies.”

“This achievement reflects the depth of cell therapy experience, scientific talent and focused execution of our organizations in both the U.S. and U.K.,” said Vijay Chiruvolu, Ph.D., Chief Technical Officer of Instil. “Additionally, the development of the product release plan, encompassing the innovative potency assay as part of QC release as well as the comprehensive characterization strategy, was built on expertise from our broad, cross-functional team including research, process development, analytical sciences and translational medicine.”

Zachary Roberts, M.D. Ph.D., Chief Medical Officer of Instil added, “We are pleased to begin this clinical trial of ITIL-168 in an area of marked unmet medical need. Furthermore, the inclusion of additional cohorts of patients who have not been systematically studied with TIL therapy provides us with the opportunity to learn about the potential role of ITIL-168 in other populations who lack effective therapies.”

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 TIL therapies for the treatment of patients with cancer and as an innovation platform for next generation therapies. 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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