Instil Bio Receives Orphan Drug Designation for ITIL-168 in Melanoma

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DALLAS, April 27, 2021 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil”) (Nasdaq: TIL) received orphan drug designation (ODD) from the U.S. Food and Drug Administration (FDA) for the treatment of melanoma stages IIB to IV with its ITIL-168 TIL therapy.

“The Orphan Drug Designation incentivizes biotech companies to develop new therapies that are important for patients. We are pleased to advance development of ITIL-168 for the treatment of melanoma stages IIB to IV with this designation,” said Bronson Crouch, Chief Executive Officer of Instil.

Orphan Drug Designation confers potential benefits to sponsors, including tax credits for qualified clinical testing, waiver of BLA user fees, and eligibility of market exclusivity for 7 years upon marketing approval.

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, whether, if approved, these product candidates will be successfully distributed and marketed, and the potential benefits of orphan drug designation to ITIL-168. 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.

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