Instil Bio Announces U.S. F.D.A. Clearance of Investigational New Drug (IND) Application for AXN-2510, a PD-L1xVEGF Bispecific Antibody, for a Phase 1 Trial in Relapsed/Refractory Solid Tumors

July 2, 2025

US phase 1 trial of ‘2510 is expected to be initiated before the end of 2025

Anticipate ImmuneOnco sharing initial safety and efficacy results from phase 2 trial of ‘2510 + chemo in 1L NSCLC in the second half of 2025

DALLAS, July 02, 2025 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil”) (NASDAQ: TIL), a clinical-stage biopharmaceutical company focused on developing a pipeline of novel therapies, today announced the clearance of an Investigational New Drug (IND) application for AXN-2510 (“‘2510”) by the U.S. Food and Drug Administration.

Instil expects to initiate a phase 1 trial of ‘2510 as monotherapy for patients with relapsed/refractory solid tumors before the end of 2025. The trial is designed to evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of ‘2510 in patients with solid tumors. Additionally, Instil continues to anticipate that initial safety and efficacy results from the ongoing phase 2 study of ‘2510 in combination with chemotherapy in first-line NSCLC in China will be shared in the second half of 2025 by ImmuneOnco.

“We are pleased to announce the clearance of the ‘2510 IND by the FDA,” said Jamie Freedman, M.D., Ph.D., Chief Medical Officer of Instil. “Evaluating ‘2510 in a global population will be a critical milestone in the clinical development of ‘2510.”

About Instil Bio

Instil Bio is a clinical-stage biopharmaceutical company focused on developing a pipeline of novel therapies. Instil's lead asset, AXN-2510, is a novel and differentiated PD-L1xVEGF bispecific antibody in development for the treatment of multiple solid tumors. For more information, visit www.instilbio.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words (and variations of words) such as "anticipates," "believes," "could,” expects," "exploring," "future," "intends," "may," "plans," "potential," "projects," "will," “target,” and similar expressions are intended to identify forward-looking statements. Forward-looking statements include express or implied statements regarding Instil's expectations with respect to the therapeutic potential of AXN-2510, the clinical development of AXN-2510, patient enrollment and clinical trials and the timing, scope and design thereof, and the availability and timing of data from clinical trials. Forward-looking statements are based on Instil 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 in-licensing product candidates and clinical trial collaborations; the costly and time-consuming product development process and the uncertainty of clinical success; the risks inherent in relying on collaborators and other third parties, including for manufacturing and clinical trial operation; the risks and uncertainties related to successfully initiating, enrolling, completing and reporting data from 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; risks related to macroeconomic conditions, including as a result of international conflicts, U.S.-China trade and political tensions, interest rates, inflation, and other factors, which could materially and adversely affect Instil's business and operations; the risks and uncertainties associated with the time-consuming and uncertain regulatory approval process for product candidates across multiple indications and multiple regulatory authorities; the impact of product candidates that may compete with those developed by Instil; the sufficiency of Instil's cash resources; and other risks and uncertainties affecting Instil and its plans and development programs, including those discussed in the section titled "Risk Factors" in Instil's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 filed with the SEC, as well as Instil's other filings with the SEC. Additional information will be made available in other filings that Instil makes from time to time with the SEC. 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. These forward-looking statements speak only as the date hereof, and Instil disclaims any obligation to update these statements except as may be required by law.

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