Instil Bio and ImmuneOnco Announced the Phase 2 Trial in First-line NSCLC of IMM2510/AXN-2510 (‘2510), a PD-L1xVEGF Bispecific Antibody, in Combination with Chemotherapy in China is on Track to Complete Enrollment in Q3 2025; Initial Results Anticipated in 2H 2025

May 22, 2025

Phase 3 trial of ‘2510 in combination with chemotherapy in first-line NSCLC anticipated to start in mid-2026 in China, subject to regulatory discussions

Monotherapy US dose optimization Phase 1b/2 trial of ‘2510 in relapsed/refractory solid tumors, intended to bridge the doses to the ongoing China trials, replaces the previously planned US trial

DALLAS and SHANGHAI, May 22, 2025 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (Nasdaq: TIL, "Instil") and ImmuneOnco Biopharmaceuticals (Shanghai) Inc. (HKEX Code: 1541.HK, “ImmuneOnco”), today announced clinical trial updates of ‘2510 and NSCLC clinical development strategy.

“We are delighted with the significant clinical advancements by our collaborator, ImmuneOnco, with ‘2510 for NSCLC in China,” said Bronson Crouch, CEO of Instil. “We are confident that ‘2510 has the potential to emerge as a leading PD-(L)1xVEGF bispecific antibody, and we look forward to the initial results from the ongoing first-line chemotherapy combination trial in China. In parallel, we are advancing preparations to initiate U.S. clinical development later this year, and we look forward to bringing this potential important new medicine to patients globally.”

Dr. Tian Wenzhi, CEO of ImmuneOnco, said, “Our collaboration on ‘2510 has achieved meaningful progress. We are actively conducting a Phase 2 clinical trial of ‘2510 in combination with chemotherapy in patients with first-line NSCLC. The data generated to date underscore its best-in-class potential within the promising PD-(L)1xVEGF class. We anticipate sharing further clinical data in the second half of 2025.”

Phase 2 Trial of ‘2510 in Combination with Chemotherapy in First-line NSCLC

- ImmuneOnco expects to complete enrollment of approximately 60 patients in Q3 2025 in its Phase 2 trial of ‘2510 in combination with chemotherapy in patients with NSCLC in the first-line setting in China.
- Among more than 30 NSCLC patients enrolled (including the safety run-in), more than 20 first-line NSCLC patients have been treated since the end of March.
- ImmuneOnco anticipates sharing initial safety and efficacy results from this Phase 2 trial in the second half of 2025.

‘2510 Monotherapy Data in Relapsed/Refractory NSCLC (China)

- The objective response rate (ORR) is similar to datasets from competitor PD-(L)1xVEGF bispecific antibodies at a similar stage of development in patients with previously treated NSCLC, showing ORR of 23% (efficacy evaluable n=13).
- The updated clinical safety from the full ‘2510 monotherapy trial (n=106) and efficacy data in NSCLC are further detailed in a new corporate deck posted on Instil Bio’s investor relations webpage at https://ir.instilbio.com/news-events/presentations.

Other ‘2510 Clinical and Preclinical Updates

- Instil’s Phase 1b/2 trial of ‘2510 in the United States is expected to be initiated before the end of 2025, assuming the necessary regulatory approvals are obtained. The trial is expected to be a monotherapy dose optimization trial in relapsed/refractory solid tumors, which is intended to bridge the doses to the ongoing China trials and replaces the previously planned US ‘2510 and chemotherapy combination trial in first-line NSCLC.
    - Instil believes that this change may accelerate the path to initiating a potential global Phase 3 trial in first-line NSCLC.
- Preclinical assays demonstrate cooperative binding of ‘2510 to PD-L1 in the presence of VEGF *in vitro*. Further preclinical datasets demonstrating the unique and potentially best-in-class mechanism of action of ‘2510 are anticipated to be presented at future medical or scientific conferences.

About AXN-2510
AXN-2510 is a PD-L1xVEGF bispecific antibody in development for the treatment of multiple solid tumors. AXN-2510/IMM2510 is differentiated from other PD-(L)1xVEGF bispecific antibodies by its VEGF trap, which binds multiple VEGF receptor ligands beyond VEGF-A, a bispecific structure which leverages PD-L1 as an anchor in the tumor microenvironment (TME), and enhanced antibody-dependent cellular cytotoxicity (ADCC) to direct killing of PD-L1-positive tumor cells.

About ImmuneOnco
ImmuneOnco is a clinical-stage biotech company focused on discovery and development of biologics to treat cancers, autoimmune diseases and metabolic diseases. With 10+ assets all originated in-house and the most advanced asset in phase III right now, ImmuneOnco is pursuing innovative

therapies to improve patients' health. For more information visit www.immuneonco.com.

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," "expected," "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/IMM2510, the clinical development of AXN-2510/IMM2510, including IND submissions and clearances, patient enrollment and clinical trials and the timing, scope and design thereof, the availability and timing of data from clinical trials, regulatory approvals and interactions and other statements that are not historical fact. 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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