Instil Bio and ImmuneOnco Announce Global Registrational Strategy for PD-L1xVEGF Bispecific Antibody, SYN-2510/IMM2510, in Non-Small Cell Lung Cancer and Triple-Negative Breast Cancer

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- *Global registrational strategy in first-line non-squamous and squamous non-small cell lung cancer (NSCLC)*
- *Global registrational strategy in first-line triple-negative breast cancer (TNBC)*
- *Initiation of Phase 1b/2 IMM2510/SYN-2510 + chemotherapy combination in first-line NSCLC anticipated in late 2024 in China*
- *Initiation of Phase 1b/2 IMM2510/SYN-2510 + chemotherapy combination in first-line TNBC anticipated in early 2025 in China*
- *US IND submission for SYN-2510 targeted in late 2024, starting with Phase 2 trial of SYN-2510 monotherapy in second-line NSCLC*

DALLAS and SHANGHAI, Sept. 16, 2024 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (Nasdaq: TIL, "Instil") and ImmuneOnco Biopharmaceuticals (Shanghai) Inc. (HKEX:1541, “ImmuneOnco”) announced today the global registrational strategy for the PD-L1xVEGF bispecific antibody SYN-2510/IMM2510 in combination with chemotherapy in front-line non-small cell lung cancer (NSCLC) and in front-line triple-negative breast cancer (TNBC).

In China, ImmuneOnco is accelerating the development of IMM2510/SYN-2510 in front-line NSCLC by targeting initiation in late 2024 of a Phase 1b/2 front-line chemo combination study. This study is expected to enroll patients with driver gene mutation-negative non-squamous and squamous NSCLC. ImmuneOnco is also accelerating development of IMM2510/SYN-2510 in front-line TNBC with initial Phase 1b/2 chemotherapy combination studies targeted to begin in early 2025.

In the United States, Instil is prioritizing development of SYN-2510/IMM2510 in NSCLC and TNBC. US IND submission is targeted for late 2024, starting with a Phase 2 trial of SYN-2510/IMM2510 monotherapy in second-line non-squamous and squamous NSCLC.

With potential positive proof-of-concept data, ImmuneOnco and Instil may initiate joint global randomized Phase 3 chemotherapy combination trials in first-line non-squamous and squamous NSCLC and/or first-line TNBC.

“There are significant unmet medical needs in NSCLC and TNBC cancer patients which may be addressed by IMM2510,” said Dr. Wenzhi Tian, PhD, CEO and CSO of ImmuneOnco. “This practical and accelerated registrational strategy, which is aligned with Instil, paves a clear pathway to a potential regulatory approval for us in China and for Instil Bio globally.”

“SYN-2510 may have the opportunity to meaningfully improve on the current standard of care in NSCLC and TNBC,” said Bronson Crouch, CEO of Instil. “Our expectation for the initial US study of SYN-2510 is that it would lay a foundation for the efficient enrollment of potential global Phase 3 studies.”

About SYN-2510/IMM2510

SYN-2510/IMM2510 is a PD-L1xVEGF bispecific antibody in development for the treatment of multiple solid tumor cancers. SYN-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 Instil Bio

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

About ImmuneOnco

ImmuneOnco is a clinical-stage biotech company focused on discovery and development of biologics to treat cancers and other 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.

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," "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 SYN-2510/IMM2510, the clinical development of SYN-2510/IMM2510, including IND submissions and clearances, clinical studies and the timing, scope and design thereof, 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 June 30, 2024 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.

Contacts:
Investor Relations:
1-972-499-3350
investorrelations@instilbio.com
www.instilbio.com