UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 16, 2024

Instil Bio, Inc.
(Exact name of registrant as specified in its Charter)

Delaware	**001-40215**	**83-2072195**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3963 Maple Avenue, Suite 350 **Dallas, Texas**	**75219**
(Address of Principal Executive Offices)	(Zip Code)

(972) 499-3350
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.000001 par value	TIL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Instil Bio, Inc. (the "Company") from time to time presents and/or distributes to the investment community presentations related to its business. A copy of its most recent presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in this Item 7.01 and Exhibit 99.1 hereto is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 16, 2024, the Company issued a press release entitled "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". A copy of the press release is attached hereto as Exhibit 99.2 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Instil Bio Corporate Presentation dated September 2024
99.2	Press release dated September 16, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Instil Bio, Inc.

Dated: September 16, 2024

By: /s/ Sandeep Laumas, M.D.
Sandeep Laumas, M.D.
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

Instil Bio Corporate Presentation

September 2024

InstilBio

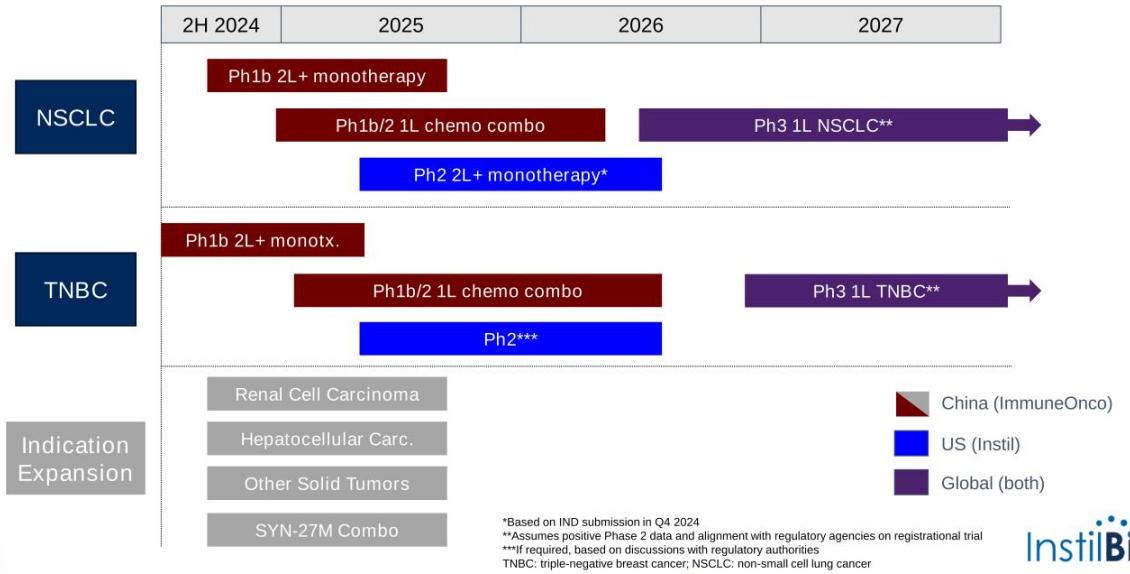
Nasdaq: TIL | www.instilbio.com

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipates,” “believes,” “expects,” "expected," “exploring,” “future,” “intends,” “may,” “plans,” “potential,” “projects,” and “will” or similar expressions are intended to identify forward-looking statements. Forward-looking statements include express or implied statements regarding our expectations with respect to the license and collaboration agreement with ImmuneOnco, the therapeutic potential of SYN-2510 and SYN-27M, our global development strategy for SYN2510 and SYN-27M,clinical development of SYN-2510 and SYN-27M, including the timing, scope and designs of clinical studies, and the generation of clinical data for SYN-2510 and SYN-27M and the timing thereof, regulatory submissions, including IND submissions and clearances, interactions and approvals and the timing thereof; concerning or implying our ability to acquire and develop new product candidates; our research, development and regulatory plans for our product candidates; our expectations regarding our capital position, resources, and balance sheet and the lease of our U.S. manufacturing facility with respect thereto, and the potential impact thereof on development of any product candidates; and other statements that are not historical fact. 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, including risks and uncertainties associated with in-licensing or acquiring additional product candidates and clinical trial collaborations; the costly and time-consuming drug product development process and the uncertainty of clinical success; the risks inherent in relying on collaborators and other third parties, including for manufacturing and generating clinical data, and the ability to rely on any such data from clinical trials in China in regulatory filings submitted to regulatory authorities outside of China; the risks and uncertainties related to successfully initiating, enrolling, completing and reporting data from clinical studies, particularly collaborator-led clinical trials, as well as the risks that results obtained in any clinical trials to date may not be indicative of results obtained in ongoing or future trials and that our product candidates may otherwise not be effective treatments in their planned indications; risks related to macroeconomic conditions, including as a result of international conflicts and U.S.-China trade and political tensions, as well as interest rates, inflation, and other factors, which could materially and adversely affect our 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 that we develop; and the sufficiency of our cash resources; and other risks and uncertainties affecting us and our plans and development programs, including those discussed in the section titled “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 filed with the SEC, as well as our other filings with the SEC. Additional information will be made available in other filings that we make 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 we disclaim any obligation to update these statements except as may be required by law.

InstilBio

Global SYN-2510/IMM2510 Development Strategy



*Based on IND submission in Q4 2024
**Assumes positive Phase 2 data and alignment with regulatory agencies on registrational trial
***If required, based on discussions with regulatory authorities
TNBC: triple-negative breast cancer; NSCLC: non-small cell lung cancer

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Key features of SYN-2510, bispecific PD-L1xVEGF antibody

Differentiated design
- PD-L1 targeting
- VEGF trap
- ADCC-enhanced

Intellectual Property
- Composition of matter coverage into 2040 (US)

Collaboration with ImmuneOnco (HKEX:1541)
- In China, opportunity to leverage proof-of-concept data generation and accelerate clinical development

Combination of validated oncology mechanisms
- PD-L1 blockade
- VEGF blockade
- PD-(L)1xVEGF bispecifics have demonstrated superiority over standard of care and/or compelling clinical activity

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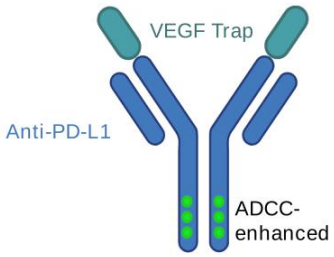
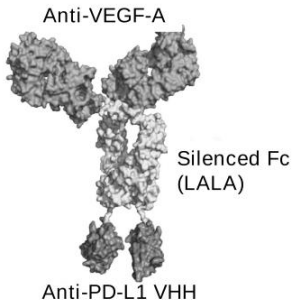
Key Competitor Landscape

	SYN-2510	BNT327 (Biotheus / BioNTech)	Ivonescimab (Akeso / Summit)
VEGF binding	VEGF-A, VEGF-B, PLGF	VEGF-A	VEGF-A
PD-1 or PD-L1	PD-L1	PD-L1	PD-1
ADCC	Enhanced ADCC	None	None
Key clinical data	Multiple responses in patients w/ prior PD-1 in Phase 1a trial	1L NSCLC*: 47% ORR 1L TNBC*: 79% ORR 2L SCLC*: 61% ORR	Superiority over Keytruda® in 1L NSCLC** Approved in 2L EGFRm NSCLC





*Source: BioNTech Q2 2024 earnings presentation
**Source: WCLC 2024 presentation

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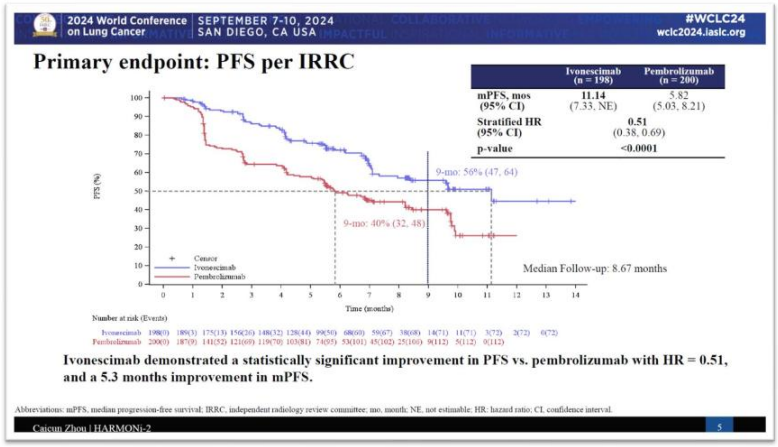
PD-1xVEGF bispecific ivonescimab has demonstrated superiority vs Keytruda®

- Ivonescimab (PD-1xVEGF bispecific) monotherapy demonstrated stat. sig. improvement in PFS vs. Keytruda® monotherapy in 1L NSCLC
- First randomized phase 3 trial reported of a regimen outperforming standard-of-care Keytruda®



Source: WCLC 2024 presentation

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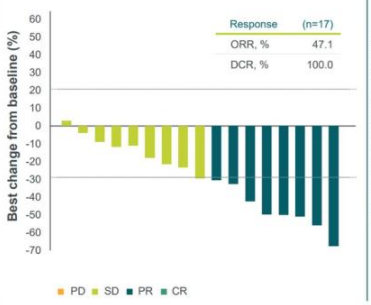
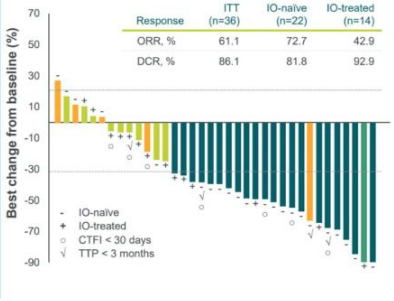
PD-L1xVEGF bispecific BNT327 has demonstrated clinical activity in multiple solid tumors

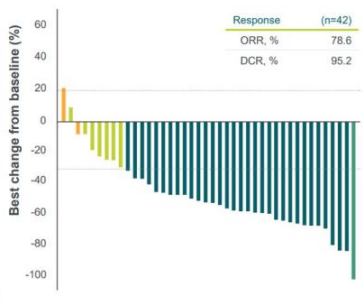
Phase 1/2 study (NCT05918445): efficacy signals in 1L NSCLC
Wu, C. et al., ASCO 2024, Poster #8533



Phase 2 (NCT05879068): clinical activity in combination with paclitaxel in 2L SCLC
Ying Cheng et al., ESMO 2023, Poster#1992P



Phase 2 (NCT05918133): clinical activity in combination with nab-paclitaxel in 1L TNBC
Jiong Wu et al., SABCS 2023, Poster #PS08-06



- BNT327 has demonstrated “Strong single compound activity, and high ORRs observed in combination with CTx in various indications”

Source: BioNTech Q2 2024 earnings presentation

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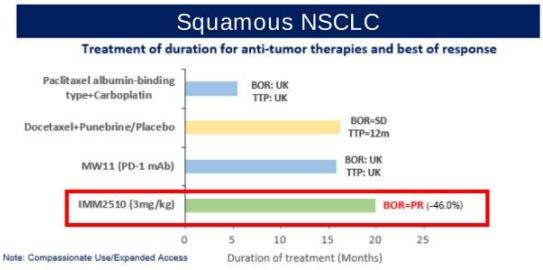
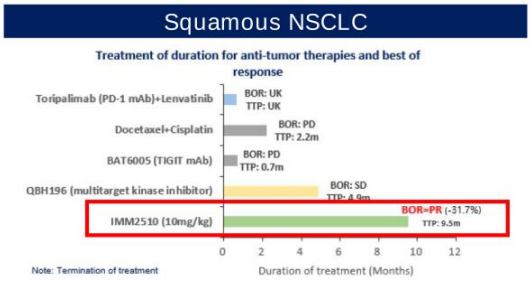
SYN-2510 achieved responses in NSCLC patients with prior PD-1 inhibitor in Phase 1a





SYN-2510 completed dose escalation up to 20 mg/kg Q2W with a manageable safety profile and no observed dose-limiting toxicities (DLT)

Source: ImmuneOnco internal company data on file

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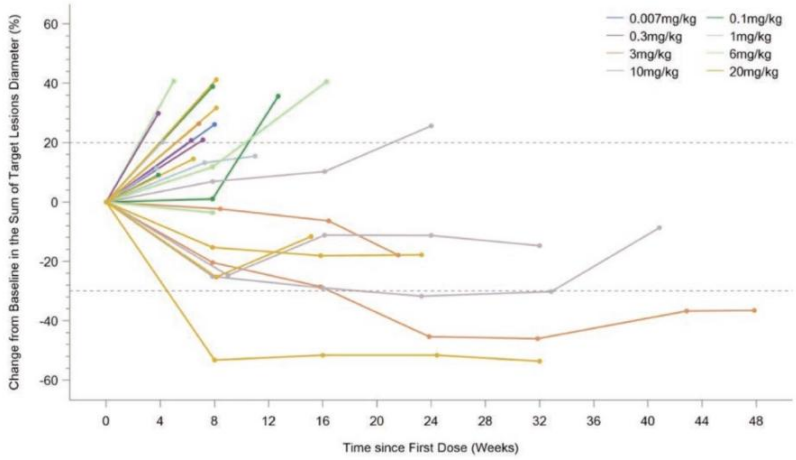
SYN-2510 achieved multiple PR and SD in dose escalation

Change in Target Lesion Tumor Size



Source: ImmuneOnco interim results for the six months ended June 30, 2024

ImmuneOnco collaboration provides opportunity to accelerate global clinical development of SYN-2510

- Collaboration with ImmuneOnco (HKEX:1541), a Hong Kong-listed biotech developing SYN-2510/IMM2510 in China
- Potential opportunities to utilize ImmuneOnco's clinical dataset:
  - Proof-of-concept in tumor types and subpopulations
  - Supporting FDA regulatory filings
  - As part of global trial to support potential registrational filings
- SynBioTx, Inc.* has exclusive rights for SYN-2510 outside of Greater China and may collaborate with ImmuneOnco for China development of SYN-2510 to expand enrollment in indications of interest, explore novel combinations, and generate data to support potential future global clinical trials

*SynBioTx, Inc. is a wholly-owned subsidiary of Instil Bio

Recent Corporate Update (Q2'24 Earnings PR)

Instil Bio Reports Second Quarter 2024 Financial Results and Provides Corporate Update

August 13, 2024 at 5:01 PM EDT

- **Executed lease of our cell therapy manufacturing facility to AstraZeneca Pharmaceuticals LP:** In July 2024, Instil reported the execution of a lease of its U.S. cell therapy manufacturing facility to AstraZeneca Pharmaceuticals LP. Under the terms of the agreement, initial base rent is greater than $7.5 million annually, and escalates at 3% per annum, with the tenant also required to pay certain operating expenses and tax expenses, subject to certain rent abatement in the first year of the 15-year lease term.

- **Cash runway expected beyond 2026.**

Second Quarter 2024 Financial and Operating Results:

As of June 30, 2024, Instil had cash, cash equivalents, marketable securities and long-term investments of $152.6 million,

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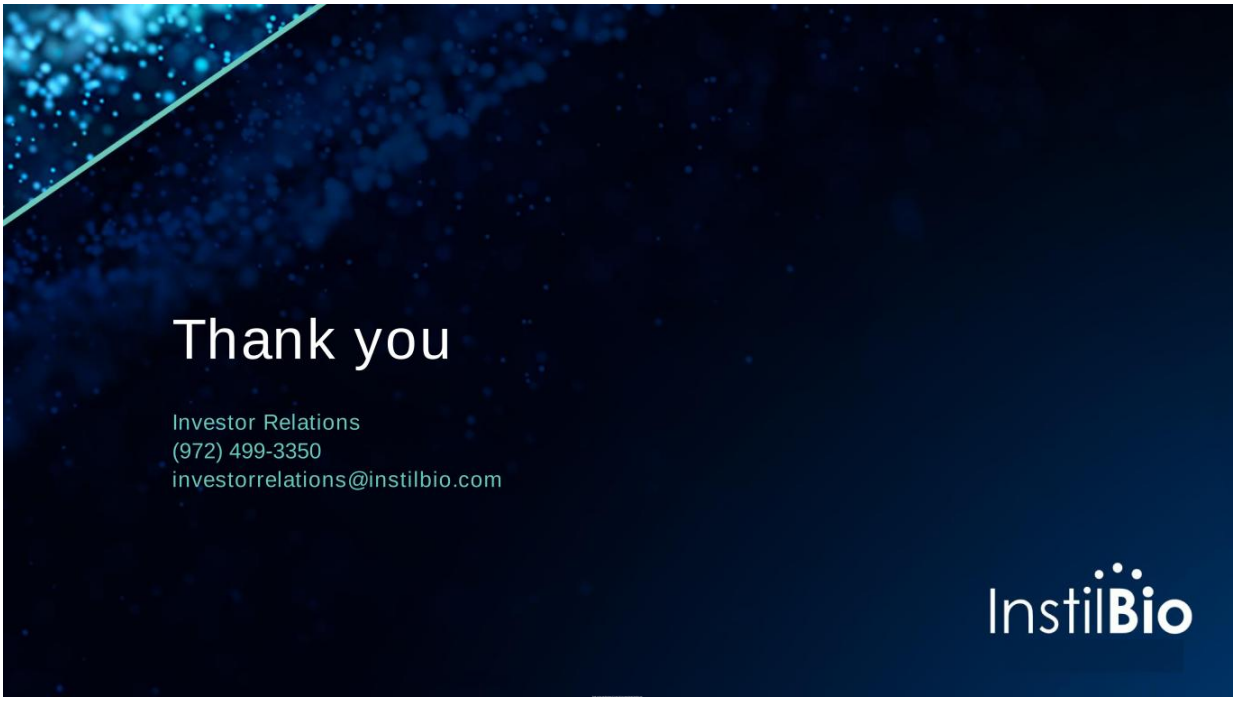
Thank you
Investor Relations
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InstilBio

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

- *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, Texas, and Shanghai, China, Sep. 16, 2024 – 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

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