Instil Bio Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

March 7, 2022

- Initiated DELTA-1, a Phase 2 trial of ITIL-168 in advanced melanoma with registrational intent

- Received orphan drug and fast-track designation from the U.S. FDA for lead pipeline candidate, ITIL-168, in melanoma

- Expansion of manufacturing capacity in Manchester, UK, with Tarzana, California facility expected online in 1H 2022

DALLAS, March 07, 2022 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil”) (NASDAQ: TIL), a clinical-stage biopharmaceutical company focused on developing tumor infiltrating lymphocyte, or TIL, therapies for the treatment of patients with cancer, today reported its fourth quarter and year end 2021 financial results and provided a corporate update.

“I am pleased with our progress in establishing our operational capabilities and initiating a clinical study in our first year as a public company,” said Bronson Crouch, Chief Executive Officer of Instil. “With the DELTA-1 Phase 2 trial of ITIL-168 underway and continued expansion of our manufacturing capabilities in both the United Kingdom and the United States, we continue to develop our platform to deliver cell therapies to patients. In 2022, we look forward to the opportunity to expand the targeted patient population for receiving our therapies in multiple indications with ITIL-168 and ITIL-306."

2021 Highlights and Anticipated Milestones:

- **Enrollment Ongoing in DELTA-1**: Instil is enrolling patients in DELTA-1, a global Phase 2 clinical trial of ITIL-168 with registrational intent in patients with advanced melanoma whose disease has progressed following PD-1 inhibitor therapy and, if BRAF-mutated, targeted therapy. Instil expects top-line safety and efficacy data in 2023 which could potentially support BLA submission and a European Medicines Agency marketing authorization application (MAA) filing.

- **INDa Cleared for DELTA-2**: Instil reported that in Q4 2021 the IND amendment was cleared for DELTA-2, a Phase 1 study of ITIL-168 in non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), cervical cancer, and cutaneous squamous cell carcinoma (CSCC).

- **Readiness to Initiate Phase 1 Study of ITIL-306 in 2022:** Instil remains on track to file an IND for a Phase 1 study of its first genetically engineered CoStAR-TIL, ITIL-306, in multiple solid tumor indications in H1 2022.

- **Presenting Pre-clinical Data on the CoStAR Platform:** Instil expects to present further pre-clinical data on the CoStAR platform, including manufacturability and in vivo models of efficacy and safety, at an upcoming scientific conference in 2022. In November 2021, Instil presented posters highlighting pre-clinical data from the CoStAR platform demonstrating how CoStAR expression led to marked enhancement of effector function and proliferation of T cells and TILs in the studies. Further details can be found in the poster publications available on the publication section of the Company's website.

- **Developing Novel CoStAR Constructs:** Instil is developing novel, proprietary families of CoStAR constructs against new targets for solid tumors beyond the initial indications targeted for ITIL-306. Instil expects to select the next CoStAR candidate for IND-enabling studies in 2022.

- **Expansion of UK Manufacturing Facility Complete:** Regulatory approval of the IMPACT manufacturing facility in Manchester, UK has been granted and clinical product manufacturing is ongoing. The opening of the IMPACT facility expands Instil’s clinical manufacturing capacity in Manchester, UK.

- **Validation of Tarzana Clinical Manufacturing Facility Ongoing:** Validation of Instil’s clinical manufacturing facility in Tarzana, California is ongoing, with availability for clinical manufacturing expected in the first half of 2022. Upon readiness of the Tarzana clinical manufacturing facility, Instil expects to achieve manufacturing capacity of up to approximately 500 patient doses per year.

Fourth Quarter Full Year 2021 Financial and Operating Results:

As of December 31, 2021, we had $37.6 million in cash and cash equivalents and $416.5 million in marketable securities, compared to $241.7 million in cash and cash equivalents and no investments in marketable securities as of December 31, 2020. The Company expects that its cash, cash equivalents and marketable securities as of December 31, 2021 will enable it to fund its operating plan into 2023.

Research and development expenses were $42.6 million and $107.3 million for the fourth quarter and full year ended December 31, 2021, compared to $10.2 million and $19.4 million for the fourth quarter and full year ended December 31, 2020, respectively.

General and administrative expenses were $11.2 million and $48.3 million for the fourth quarter and full year ended December 31, 2021, compared to $7.2 million and $14.4 million for the fourth quarter and full year ended December 31, 2020, respectively

INSTIL BIO, INC.
SELECTED FINANCIAL DATA
(Unaudited; in thousands, except share and per share amounts)

Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue	$ —	$ —	$ —	$ 138
Operating expenses:				
Research and development	42,577	10,247	107,251	19,399
General and administrative	11,175	7,230	48,309	14,383
Total operating expenses	53,752	17,477	155,560	33,782
Loss from operations	(53,752)	(17,477)	(155,560)	(33,644)
Other (expense), net	(538)	443	(1,195)	(3,943)
Loss before income tax expense	$ (54,290)	$ (17,034)	$ (156,755)	$ (37,587)
Income tax expense	(1,060)	(151)	(39)	(151)
Net loss	$ (55,350)	$ (17,185)	$ (156,794)	$ (37,738)
Net loss per share, basic and diluted	$ (0.43)	$ (1.00)	$ (1.48)	$ (2.36)
Weighted-average shares used in computing net loss per share, basic and diluted	128,952,362	17,201,427	105,993,230	15,997,794

Selected Balance Sheet Data

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 454,099	$ 241,714
Total assets	609,983	319,012
Total liabilities	54,784	26,645
Convertible preferred stock and stockholders' equity (deficit)	555,199	292,367

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 timing of our ongoing and potential future clinical trials and studies and the availability of data therefrom, including our expectations concerning the availability of top-line data from our DELTA-1 clinical trial, the initiation of a Phase 1 study of ITIL-306, and the selection of the next CoStAR candidate for IND-enabling studies, the potential for us to make submissions concerning, and for our product candidates to receive, regulatory approval from the FDA or equivalent foreign regulatory agencies and whether, if approved, these product candidates will be successfully distributed and marketed, our plans to expand clinical manufacturing capabilities, including our expectations concerning the timing and impact of opening our Tarzana facility, and the potential benefits of orphan drug designation to ITIL-168, the adequacy of our cash resources, 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 the costly and time-consuming cell therapy product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating, enrolling, reporting data from or completing 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; the ongoing COVID-19 pandemic, which could materially and adversely affect Instil's business and operations, including Instil's ability to timely initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; risks inherent in manufacturing and testing of cell therapy products; the sufficiency of Instil's cash resources, and other risks and uncertainties affecting Instil and its development programs, including those discussed in the section titled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 available on the SEC's website at www.sec.gov, and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 to be filed with the SEC. 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. 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 of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

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