Shattuck Labs Reports Second Quarter 2021 Financial Results and Upcoming Phase 1 Dose Escalation Data for SL-172154 and SL-279252

August 11, 2021

– Announced submission of abstracts for the initial Phase 1 dose-escalation data from both SL-172154 in ovarian cancer and SL-279252 in advanced solid tumors for presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2021 –

– Reported initial safety data from SL-172154 (SIRPα-Fc-CD40L) Phase 1 trial in ovarian cancer suggesting an encouraging early safety profile and ability to dose escalate beyond prior CD40 agonist antibodies –

– Announced plans to study SL-172154 in hematologic malignancies, Acute Myeloid Leukemia (AML) and Higher-Risk Myelodysplastic Syndromes (HR-MDS), with an IND filing anticipated in the fourth quarter of 2021 –

– Reported plans to continue dose escalating in the SL-279252 (PD1-Fc-OX40L) Phase 1 trial in advanced solid tumors based on trends in immune response data –

AUSTIN, TX and DURHAM, NC, Aug. 11, 2021 (GLOBE NEWSWIRE) -- Shattuck Labs, Inc. (Shattuck) (NASDAQ: STTK), a clinical-stage biotechnology company pioneering the development of bi-functional fusion proteins as a new class of biologic medicine for the treatment of patients with cancer and autoimmune disease, today reported financial results for the second quarter ended June 30, 2021 and provided recent business highlights.

“Over the past quarter we have begun to compare and contrast the immunological effects of CD40 and OX40 stimulation in cancer patients treated with SL-172154 and SL-279252. We believe the emerging data validate the hypothesis that the ARC platform can uniquely activate the TNF superfamily and indicate that the effects of OX40 stimulation are far more subtle than innate immune stimulation of CD40. We are excited to share this data in just a few months' time at the SITC Annual Meeting,” said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. “Discharging the perceived safety risks associated with dose-escalating a CD40 agonist has enabled us to broaden our clinical development strategy, including an expected IND application for expansion into both Acute Myeloid Leukemia and Higher Risk Myelodysplastic Syndrome in the fourth quarter of this year.”

Second Quarter 2021 Recent Business Highlights and Other Recent Developments

ARC Clinical-Stage Pipeline

- **Continued Enrollment of SL-172154 Phase 1 Clinical Trial in Ovarian Cancer with Encouraging Safety Profile:** The phase 1 trial is an open label, multi-center, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 administered intravenously in patients with platinum resistant ovarian cancer. SL-172154 is a dual CD47/SIRPα inhibitor and CD40 agonist. Today, Shattuck reported continued enrollment at the fourth dose level, 3.0 mg/kg, and plans to advance to the next dose level, 10.0 mg/kg. To date, no evidence of anemia, thrombocytopenia, cytokine release syndrome or liver dysfunction, nor other dose-limiting toxicities have been observed. Prior CD40 agonist antibodies have encountered dose limiting toxicities at doses of greater than 0.3 mg/kg. Initial dose-escalation data from the trial have been submitted for presentation at the SITC Annual Meeting, to be held in November 2021.
- **Anticipated IND Application for SL-172154 in AML and HR-MDS:** Shattuck plans to submit to the U.S. Food and Drug Administration an investigational new drug application for a phase 1A/B clinical trial for SL-172154 in patients with AML and HR-MDS, anticipated in the fourth quarter of 2021. The trial will evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154, as both monotherapy and in combination. In AML, Shattuck plans to evaluate SL-172154 in combination with both azacitidine and venetoclax. In both HR-MDS and TP53 mutant AML, Shattuck plans to evaluate SL-172154 in combination with azacitidine.
- **Continued Enrollment of SL-172154 Phase 1 Clinical Trial in Squamous Cell Carcinoma of the Head and Neck or Skin:** Shattuck continues to enroll patients in a Phase 1 clinical trial for SL-172154, administered intratumorally, in patients with squamous cell carcinoma of the head and neck or skin. The Phase 1 trial will evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 as monotherapy. Initial dose-escalation data from the trial are expected in the first half of 2022.
- **Additional Dose Escalation Cohorts Added to the SL-279252 Phase 1 Clinical Trial:** An analysis of data collected across a dose range of 0.0001 through 6.0 mg/kg, on two dosing schedules, demonstrated dose dependent OX40 receptor engagement of OX40 expressing T cells, and a primary pharmacodynamic effect showing rapid egress of these target cells from circulation. This effect has not been reported for prior OX40 agonist antibodies. No dose-limiting toxicities have been observed to date. Based on these data Shattuck plans to enroll additional patients at dose levels of 12.0 and 24.0 mg/kg. Because very few of the patients treated to date are known to express PD-L1 within the tumor, Shattuck plans to enroll patients with known PD-L1 positive tumors in the additional dose level cohorts. The Phase 1 trial is an open label, multi-

center, dose escalation, and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-279252 as monotherapy in patients with advanced solid tumors. SL-279252 is currently being developed in collaboration with Takeda Pharmaceuticals. An abstract containing data from the dose-escalation cohorts through 6.0 mg/kg has been submitted to the SITC Annual Meeting, to be held in November 2021.

Corporate

- **Appointed Chief Technical Officer**: In June 2021, Abhinav A. Shukla was appointed Chief Technical Officer. Prior to joining Shattuck, Dr. Shukla was the Chief Technical Operations Officer at Redpin Therapeutics and was responsible for all aspects of process, analytical and formulation development, and cGMP manufacturing. Previously he held several senior leadership positions, including Vice President of Manufacturing at CRISPR Therapeutics, Vice President and Head of Biologics Process Development at Shire, and Senior Vice President of Process Development and Manufacturing at KBI Biopharma. Shukla received his doctorate in Chemical and Biochemical Engineering from Rensselaer Polytechnic Institute and his undergraduate degree from the Indian Institute of Technology, Delhi.

Second Quarter 2021 Financial Results

- **Cash Position:** As of June 30, 2021, cash and cash equivalents and short-term investments were $304.8 million, as compared to $335.4 million as of December 31, 2020.
- **Collaboration Revenue:** Revenue for the second quarter ended June 30, 2021 was $(4.2) million, as compared to $3.2 million for the second quarter ended June 30, 2020. The negative revenue was driven by increased expected costs required to complete the performance obligation contained in the Collaboration Agreement with Takeda as a result of changes to the SL-279252 clinical development plan.
- **Research and Development (R&D) Expenses:** R&D expenses for the second quarter ended June 30, 2021 were $14.9 million, as compared to $7.8 million for the second quarter ended June 30, 2020. The increase was primarily driven by increases in clinical development, manufacturing, personnel-related costs, and laboratory capabilities.
- **General and Administrative (G&A) Expenses:** G&A expenses for the second quarter ended June 30, 2021, were $5.4 million, as compared to $1.7 million for the second quarter ended June 30, 2020. The increase was primarily driven by an increase in personnel related costs to support the operational expansion and costs associated with being a public company.
- **Net Loss:** Net loss was $23.6 million for the second quarter ended June 30, 2021, or $0.56 per basic and diluted share, as compared to a net loss of $6.2 million for the second quarter ended June 30, 2020, or $0.81 per basic and diluted share.

2021 Financial Guidance

Shattuck believes its cash and cash equivalents and short-term investments will be sufficient to fund its operations through 2024, which is beyond results from its Phase 1 clinical trials of SL-172154 and SL-279252. This cash runway guidance is based on the Company's current operational plans and excludes any additional funding that may be received or business development or additional clinical development activities that may be undertaken.

About SL-172154

SL-172154 is an investigational bi-functional fusion protein designed to block the CD47 immune checkpoint and simultaneously agonize the CD40 pathway. SL-172154 is currently being evaluated in Phase 1 clinical trials for the treatment of patients with ovarian and head and neck or skin squamous cell carcinoma.

In preclinical studies, SL-172154, demonstrated evidence of bridging the innate and adaptive immunity, antigen cross-priming to CD8+ T cells, and durable receptor occupancy, leading to superior anti-tumor activity over anti-CD47 antibodies, and anti-CD40 antibodies, both alone or in combination. Additionally, SL-172154 preclinically demonstrated a favorable safety profile with no evidence of hematologic toxicities observed with other CD47 inhibitors.

About SL-279252

SL-279252 is an investigational bi-functional fusion protein designed to block the PD-1 immune checkpoint and simultaneously agonize the OX40 pathway. SL-279252 is currently being evaluated in a Phase 1 clinical trial for the treatment of patients with advanced solid tumors and lymphoma. SL-279252 is part of a collaboration with Takeda Pharmaceuticals.

In preclinical studies, SL-279252, demonstrated evidence of high monotherapy activity, potent stimulation of OX40+ T Cells and superior anti-tumor activity over Anti-PD1/L-1 antibodies and Anti-OX40 antibodies, both alone or in combination.

About Shattuck Labs, Inc.

Shattuck is a clinical-stage biotechnology company pioneering the development of bi-functional fusion proteins as a new class of biologic medicine for the treatment of patients with cancer and autoimmune disease. Compounds derived from Shattuck's proprietary Agonist Redirected Checkpoint, ARC®, platform simultaneously inhibit checkpoint molecules and activate costimulatory molecules within a single therapeutic. The company's lead wholly owned program, SL-172154 (SIRPα-Fc-CD40L), which is designed to block the CD47 immune checkpoint and simultaneously agonize the CD40 pathway, is being evaluated in a Phase 1 trial. A second compound, SL-279252 (PD1-Fc-OX40L), is being evaluated in a Phase 1 trial in collaboration with Takeda Pharmaceuticals. Additionally, the company is advancing a proprietary Gamma Delta T Cell Engager, GADLEN™, platform,

which is designed to bridge gamma delta T cells to tumor antigens for the treatment of patients with cancer. Shattuck has offices in both Austin, Texas and Durham, North Carolina. For more information, please visit: www.ShattuckLabs.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, our expectations regarding plans for our preclinical studies, clinical trials and research and development programs, the initiation of any dose-expansion cohorts, the anticipated timing of the results from those studies and trials, the anticipated timing for IND filings, anticipated timing for preclinical development updates, the potential for our proprietary ARC technology and GADLEN platform, the clinical benefit of TIGIT blocking antibodies and T cell engagers, additional uses for our proprietary ARC technology and GADLEN platform, potential new uses for our product candidates, and expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While we believe these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in our filings with the U.S. Securities and Exchange Commission (the "SEC")), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: the recent and ongoing COVID-19 pandemic and associated public health guidance measures; expectations regarding the initiation, progress, and expected results of our preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of our Phase 1 clinical trials; the unpredictable relationship between preclinical study results and clinical study results; the timing or likelihood of regulatory filings and approvals; liquidity and capital resources; and other risks and uncertainties identified in our Annual Report on Form 10-K for the year ended December 31, 2020 and subsequent periodic and current reports filed with the SEC. We claim the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

The Company intends to use the investor relations portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

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SHATTUCK LABS, INC.
BALANCE SHEETS
(In thousands)

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 86,494	$ 157,898
Short-term investments	218,304	177,551
Prepaid expenses and other current assets	11,080	10,190
Total current assets	315,878	345,639
Property and equipment, net	7,571	3,000
Other assets	331	349
Total assets	$ 323,780	$ 348,988
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,007	$ 1,754
Accrued expenses	11,326	7,352
Deferred revenue	2,778	7,728
Total current liabilities	15,111	16,834
Deferred revenue, net of current portion	29,215	21,306
Deferred rent	2,367	987
Total liabilities	46,693	39,127
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	386,206	382,012

Accumulated other comprehensive loss	(1,620)	(63)
Accumulated deficit	(107,504)	(72,093)
Total stockholders' equity	277,087	309,861
Total liabilities and stockholders' equity	$ 323,780	$ 348,988

SHATTUCK LABS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue - related party	$ (4,231)	$ 3,181	$ (1,961)	$ 6,157
Operating expenses:				
Research and development	14,882	7,755	25,219	15,892
General and administrative	5,399	1,746	9,755	3,346
Expense from operations	20,281	9,501	34,974	19,238
Loss from operations	(24,512)	(6,320)	(36,935)	(13,081)
Other income (expense):				
Interest income	1,000	138	1,696	387
Other	(86)	(26)	(172)	(68)
Total other income	914	112	1,524	319
Net loss	$ (23,598)	$ (6,208)	$ (35,411)	$ (12,762)
Unrealized loss on short-term investments	(960)	(97)	(1,557)	(36)
Comprehensive loss	$ (24,558)	$ (6,305)	$ (36,968)	$ (12,798)
Net loss per share – basic and diluted	$ (0.56)	$ (0.81)	$ (0.85)	$ (1.67)
Weighted-average shares outstanding – basic and diluted	41,906,268	7,646,149	41,840,555	7,633,565

Source: Shattuck Labs, Inc.