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Shattuck Labs Reports Second Quarter 2022 Financial Results and Recent Business Highlights

– Enrollment of Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in platinum-resistant ovarian cancer expected to begin in Q3'2022 with initial combination data expected in 1H'2023 –

– Dose escalation ongoing for Phase 1 clinical trial of SL-172154 in acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (HR-MDS) with initial monotherapy and combination dose-escalation data expected in 1H'2023 –

– Presented preclinical proof-of-concept data demonstrating the potential of the Gamma Delta T Cell Engager (GADLEN) platform to direct human gamma delta T cells to kill human tumor cells –

AUSTIN, TX and DURHAM, NC, Aug. 11, 2022 (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 quarter ended June 30, 2022 and provided recent business highlights.

"We have made significant progress throughout the second quarter, including dosing patients in our Phase 1 clinical trial of SL-172154 in AML and HR-MDS and advancing SL-172154 in our clinical trial in platinum-resistant ovarian cancer," said Taylor Schreiber, M.D., Ph.D., and Chief Executive Officer of Shattuck. "As we look ahead to the second half of this year, we look forward to beginning to enroll patients at immunologically active dose levels of SL-172154 in combination with liposomal doxorubicin for patients with advanced platinum-resistant ovarian cancer and with azacitidine for patients with AML and HR-MDS. We also continue to make excellent progress advancing our preclinical pipeline from our ARC and GADLEN platforms, and we expect to nominate the next clinical product candidate by the end of this year."

Second Quarter 2022 Recent Business Highlights and Other Recent Developments

ARC Clinical-Stage Pipeline and Preclinical Pipeline

SL-172154 (SIRPα-Fc-CD40L)

- **Continued Enrollment of SL-172154 Phase 1 Monotherapy Dose-Escalation Clinical Trial in Platinum-Resistant Ovarian Cancer:** This open-label, multi-center, dose-escalation clinical trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 administered intravenously in patients with advanced platinum-resistant ovarian cancer. To date, Shattuck has dose escalated to the anticipated top dose level of 10.0 mg/kg. Most patients at both the 3.0 mg/kg and 10.0 mg/kg dose levels have experienced grade 2 infusion related reactions, which did not lead to any treatment discontinuations. In one of five patients treated at the 10.0 mg/kg dose level, we observed a dose limiting toxicity of alanine transaminase increase. Preliminary data suggest that extending the duration of infusion may reduce the incidence of infusion related reactions. We are currently enrolling additional patients at 3.0 mg/kg with an extended infusion time. To date, we have observed no evidence of destructive anemia in any patient treated. We have observed full receptor occupancy and receptor saturation of CD40 and CD47 at the 3.0 mg/kg dose level and data indicate that both serum cytokine elevations and margination of CD40+ B cells and monocytes have achieved a maximal plateau at doses of 3.0 mg/kg and 10.0 mg/kg. Dose-escalation data from the trial are expected in the first half of 2023.

- **Combination Trial of SL-172154 with Liposomal Doxorubicin Expected to Begin in the Third Quarter of 2022:** This trial will evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamics effects of SL-172154 in combination with liposomal doxorubicin in patients with advanced platinum-resistant ovarian cancer and is anticipated to begin enrollment in the third quarter of 2022. Our starting dose of SL-172154 in this trial is 3.0 mg/kg. Initial combination data from the trial are expected in the first half of 2023.

- **Enrollment Continues in SL-172154 Phase 1A/B Clinical Trial in AML and HR-MDS:** The trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 as both monotherapy and in combination. Our starting dose of SL-172154 in the monotherapy portion of this clinical trial is 1.0 mg/kg. In AML, SL-172154 will be evaluated in combination with both azacitidine and venetoclax. In both HR-MDS and TP53 mutant AML, SL-172154 will be combined with azacitidine. We plan to dose escalate as both monotherapy and in combination in a parallel staggered manner. Initial dose-escalation and combination data from the trial are expected in the first half of 2023.
- **Provided Clinical Data for Intratumorally Administered SL-172154 in Phase 1 Clinical Trial in Squamous Cell Carcinoma of the Head and Neck (HNSCC) or Skin (CSCC)**: As of the data cut-off date of April 8, 2022, five patients with cancer, four with CSCC and one with HNSCC, were treated with intratumoral administration of SL-172154 across two dose levels, 0.003 and 0.01 mg. All patients had prior anticancer surgery, four out of five patients had prior radiotherapy, and all patients had prior systemic therapy, with a median of two prior lines. SL-172154 was well tolerated at the two dose levels studied with no dose-limiting toxicities reported, and no significant safety signals were noted. An unconfirmed partial response was observed in a patient with CSCC who experienced a 75 percent reduction in the target lesion, and stable disease was observed in an additional CSCC patient. Increases in CD80, a marker of CD40 activation, have been observed in on-treatment tumor biopsies. Based on the totality of the safety and biomarker data collected to date in the ongoing Phase 1 clinical trial in ovarian cancer patients, Shattuck has decided to focus on developing SL-172154 as an intravenously administered product candidate.

SL-279252 (PD1-Fc-OX40L)

- **Continued Enrollment of SL-279252 Phase 1 Dose-Escalation Clinical Trial in Advanced Solid Tumors:** Enrollment of patients with primarily PD-L1 selected tumors continues in the Phase 1 open-label, multi-center, dose-escalation clinical trial to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity and pharmacodynamic effects of SL-279252 in patients with advanced solid tumors and lymphoma. Top-line data from the Phase 1 trial are anticipated in the second half of 2022.

Preclinical

- **Presented Preclinical Development of Gamma Delta T Cell Engager, or GADLEN, platform at the 3rd Gamma Delta T Therapies Summit in July 2022:** Data were presented demonstrating preclinical proof of concept for Shattuck's butyrophilin heterodimer-based gamma delta T cell engager platform. Data from CD19, CD20, and B7-H3-targeted GADLEN constructs demonstrated the newly described role of co-stimulation during Vg9d2 T cell activation and tumor cell killing. *In vivo* proof-of-concept data was also presented establishing the ability of the CD20-GADLEN to activate human Vg9d2 T cells to target and serially deplete CD20-expressing human B-cells in a dose-dependent, and highly specific, manner.
- **Presented Preclinical Development of SL-9258 at the PEGS Conference in May of 2022 and Published the Associated Preclinical Manuscript in the Journal of Immunology in July 2022:** SL-9258 (TIGIT-Fc-LIGHT), a dual TIGIT inhibitor and HVEM/LTβR agonist, was shown to induce potent anti-tumor immunity in preclinical mouse models of checkpoint primary and acquired resistance, both alone and when combined with anti-PD1 or anti-PDL1, through the simultaneous blockade of the TIGIT checkpoint pathway and broad immune activation of T, NK, and myeloid cells through the TNF-costimulatory ligand known as LIGHT.
- **Clinical Pipeline Product Candidate to be Selected in 2022:** As Shattuck looks to advance its preclinical pipeline, a new clinical product candidate from our ARC or GADLEN platform is anticipated to be announced in the second half of 2022.

Upcoming Events

- **Citi's 17th Annual BioPharma Conference:** Management will participate in investor one-on-one meetings and a fireside chat at Citi's 17th Annual BioPharma Conference from September 7-8, 2022.
- **H.C. Wainwright 24th Annual Global Investment Conference:** Management will participate in investor one-on-one meetings and give a corporate presentation during the H.C. Wainwright 24th Annual Global Investment Conference from September 12-14, 2022.
- Live and archived audio webcasts of both the fireside chat and presentation will be available by visiting the Events & Presentations section of the Company's website.

Second Quarter 2022 Financial Results

- **Cash Position:** As of June 30, 2022, cash and cash equivalents and short-term investments were $214.2 million, as compared to $268.8 million as of December 31, 2021.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended June 30, 2022 were $23.0 million, as compared to $14.9 million for the quarter ended June 30, 2021. This increase was primarily driven by increases in process development costs and manufacturing of trial materials to support clinical development of SL-172154, lab supplies, and personnel-related costs.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended June 30, 2022 were $4.8 million, as compared to $5.4 million for the quarter ended June 30, 2021. This decrease was primarily

driven by decreases in personnel-related and other operating costs.
- **Net Loss:** Net loss was $27.4 million for the quarter ended June 30, 2022, or $0.65 per basic and diluted share, as compared to a net loss of $23.6 million for the quarter ended June 30, 2021, or $0.56 per basic and diluted share.

2022 Financial Guidance
Shattuck believes its cash and cash equivalents and short-term investments will be sufficient to fund its operations into the second half of 2024, 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 addition funding that may be received, proceeds from business development transactions, or additional costs associated with clinical development activities that may be undertaken.

About SL-172154
SL-172154 (SIRPα-Fc-CD40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the CD47/SIRPα checkpoint interaction and activate the CD40 costimulatory receptor to bolster an anti-tumor immune response in patients with advanced cancer. Multiple Phase 1 clinical trials are ongoing for patients with advanced platinum-resistant ovarian cancer (NCT04406623, NCT05483933) and patients with AML and HR-MDS (NCT05275439).

About SL-279252
SL-279252 (PD1-Fc-OX40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the PD-1/PD-L1 interaction and activate the OX40 receptor in patients with advanced cancers. A Phase 1 trial in patients with solid tumors and lymphoma is ongoing (NCT03894618).

About Shattuck Labs, Inc.
Shattuck Labs, Inc. (NASDAQ: STTK) 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 with a single therapeutic. The company's SL-172154 (SIRPα-Fc-CD40L) program, which is designed to block the CD47 immune checkpoint and simultaneously agonize the CD40 pathway, is being evaluated in multiple Phase 1 trials. A second product candidate, SL-279252 (PD1-Fc-OX40L), is being evaluated in a Phase 1 trial in solid tumors or lymphomas. 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 anticipated timing for enrollment of our clinical trials, the anticipated timing of the results from our preclinical studies and clinical trials, anticipated timing for preclinical development updates, potential clinical benefit of 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; 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 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, 2021, and subsequent disclosure documents 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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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

SHATTUCK LABS, INC.
BALANCE SHEETS

(In thousands)

	June 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 37,870	$ 92,268
Investments	176,370	176,536
Prepaid expenses and other current assets	15,177	19,462
Total current assets	229,417	288,266
Property and equipment, net	18,759	9,938
Other assets	3,164	381
Total assets	$ 251,340	$ 298,585
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,674	$ 10,012
Accrued expenses and other current liabilities	18,571	14,574
Total current liabilities	24,245	24,586
Non-current operating lease liabilities	4,566	—
Deferred rent	—	2,213
Total liabilities	28,811	26,799
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	392,598	389,408
Accumulated other comprehensive loss	(1,108)	(560)
Accumulated deficit	(168,966)	(117,067)
Total stockholders' equity	222,529	271,786
Total liabilities and stockholders' equity	$ 251,340	$ 298,585

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,	
	2022	2021	2022	2021
Collaboration revenue	$ 50	$ (4,231)	$ 50	$ (1,961)
Operating expenses:				

Research and development	22,963	14,882	42,150	25,219
General and administrative	4,745	5,399	9,724	9,755
Expense from operations	27,708	20,281	51,874	34,974
Loss from operations	(27,658)	(24,512)	(51,824)	(36,935)
Other income (expense):				
Other	287	914	(75)	1,524
Net loss	$ (27,371)	$ (23,598)	$ (51,899)	$ (35,411)
Unrealized loss on investments	(581)	(960)	(548)	(1,557)
Comprehensive loss	$ (27,952)	$ (24,558)	$ (52,447)	$ (36,968)
Net loss per share – basic and diluted	$ (0.65)	$ (0.56)	$ (1.22)	$ (0.85)
Weighted-average shares outstanding – basic and diluted	42,380,454	41,906,268	42,369,102	41,840,555