# Shattuck Labs Reports First Quarter 2022 Financial Results and Recent Business Highlights

May 12, 2022

*– Dose escalation ongoing in Phase 1 clinical trial of SL-172154 in platinum-resistant ovarian cancer; combination trial with liposomal doxorubicin on track to begin in 2H'2022; full dose-escalation data in monotherapy and initial data in combination both expected in 1H'2023 –*

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

*– Enrollment ongoing for Phase 1 dose-escalation trial of SL-279252 with top-line data expected in 2H'2022 –*

AUSTIN, TX and DURHAM, NC, May 12, 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 March 31, 2022 and provided recent business highlights.

"We are now completing the monotherapy dose-escalation study for SL-172154 in ovarian cancer patients and are focused on the initiation and rapid clinical execution of multiple combination studies in both hematologic and solid tumors. This expansion is a critical step in establishing SL-172154 as both a first- and best-in-class CD47 inhibitor and CD40 agonist, and we continue to expect SL-172154 to differentiate from other CD47 inhibitors and CD40 agonists in terms of safety, pharmacodynamic activity, and efficacy in combinations. The next 18 months are shaping up to be a defining period for establishing CD47 inhibition as a key macrophage checkpoint in multiple indications, and we look forward to providing initial combination data from SL-172154 in the first half of 2023," said Taylor Schreiber, M.D., Ph.D., and Chief Executive Officer of Shattuck.

**First 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 1A 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 platinum resistant ovarian cancer. Full dose-escalation data from the trial are expected in the first half of 2023.
- **Phase 1B Clinical Trial of SL-172154 in Combination with Liposomal Doxorubicin Expected to Begin in the Second Half of 2022:** This clinical 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 second half of 2022. Initial combination data from the trial are expected in the first half of 2023. Additional combination trials with SL-172154 in ovarian cancer and novel agents are currently being planned.
- **Enrollment Continues in SL-172154 Phase 1A/B Clinical Trial in Acute Myeloid Leukemia (AML) and Higher-Risk Myelodysplastic Syndromes (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. In both HR-MDS and TP53 mutant AML, SL-172154 will be combined with azacitidine. In AML, SL-172154 will be evaluated in combination with both azacitidine and venetoclax. Initial data from the monotherapy and combination dose escalation portions of the trial are expected in the first half of 2023.
- **Data for Intratumorally Administered SL-172154 Phase 1 Clinical Trial in Squamous Cell Carcinoma of the Head and Neck or Skin to be Presented in the Second Half of 2022:** Shattuck anticipates presenting data from the clinical trial in the second half of 2022. Shattuck may continue further development of SL-172154 in squamous cell carcinoma of the head and neck (HNSCC) or skin (CSCC) via intravenous administration following selection of a recommended Phase 2 dose in ovarian cancer.

**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 all treated subjects across the full dose range are anticipated in the second half of 2022.

**Preclinical**

- **Presented Preclinical Data on SL-9258 at AACR in April:** Preclinical data for SL-9258 (TIGIT-Fc-LIGHT), a dual TIGIT inhibitor and HVEM/LTβR agonist, were presented at the American Association for Cancer Research Annual Meeting (AACR) in April 2022. These data, from studies in a mouse model, provided preclinical evidence for anti-tumor activity of the murine equivalent of SL-9258 in PD-1 acquired resistant tumors and increased tumor rejection in comparison to TIGIT blocking antibodies. In these preclinical models, TIGIT-Fc-LIGHT outperformed TIGIT blocking antibodies independent of PD-L1 or DNAM-1 (CD226) expression. TIGIT-Fc-LIGHT was also evaluated and well tolerated in non-human primates and observed similar on-target pharmacodynamic activity to what was characterized in the mouse model. Together, these results suggest that TIGIT-Fc-LIGHT may provide clinical benefit to patients that are refractory to conventional checkpoint blockade therapy.
- **Presented Preclinical Data at AACR on GADLEN Platform:** Shattuck also presented preclinical data highlighting the potential of GADLENs to direct gamma delta T cells to kill tumor cells and, in the process, further elucidate tumor cell markers which are important for the therapeutic activity of gamma delta T cell-based therapies. Butyrophilin heterodimeric fusion proteins from Shattuck's GADLEN platform showed enhanced tumor cell killing targeting CD19 and CD20 and demonstrated preclinical proof of concept in the treatment of cancer.
- **Clinical Pipeline Product Candidate to be Selected in 2022:** As Shattuck looks to advance its preclinical pipeline, a new product candidate from the ARC or GADLEN platform is anticipated to be selected in the second half of 2022.

**Upcoming Events**

**H.C. Wainwright 2022 Global Investment Conference**

Management will participate in investor one-on-one meetings and give a corporate presentation during the H.C. Wainwright 2022 Global Investment Conference from May 24-26, 2022. A live and archived audio webcast of the presentation will be available by visiting the Events & Presentations section of the Company's website.

**First Quarter 2022 Financial Results**

- **Cash Position:** As of March 31, 2022, cash and cash equivalents and short-term investments were $239.2 million, as compared to $321.2 million as of March 31, 2021.
- **Research and Development (R&D) Expenses:** R&D expenses were $19.2 million for the quarter ended March 31, 2022, as compared to $10.3 million for the quarter ended March 31, 2021. This increase was primarily driven by increases in process development costs and manufacturing of trial materials and personnel-related costs.
- **General and Administrative (G&A) Expenses:** G&A expenses were $5.0 million for the quarter ended March 31, 2022, as compared to $4.4 million for the quarter ended March 31, 2021. This increase was primarily driven by increases in compensation related and other operating costs.
- **Net Income/Loss:** Net loss was $24.5 million for the quarter ended March 31, 2022, or $0.58 per basic and diluted share, as compared to a net loss of $11.8 million for the quarter ended March 31, 2021, or $0.28 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 additional funding that may be received or business development or additional 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. Two Phase 1 clinical trials are ongoing, the first for patients with advanced and platinum resistant ovarian cancer (NCT04406623) and the second for 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 within 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 two 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, filed on March 15, 2022 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.

**Investor & Media Contact:**
Conor Richardson
Senior Director, Finance & Investor Relations
Shattuck Labs, Inc.
InvestorRelations@shattucklabs.com

## PART I - FINANCIAL INFORMATION

### Item 1. Financial Statements

**SHATTUCK LABS, INC.**
**BALANCE SHEETS**

**(In thousands)**

| | March 31, 2022 (unaudited) | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 50,743 | $ 92,268 |
| Investments | 188,482 | 176,536 |
| Prepaid expenses and other current assets | 15,763 | 19,462 |
| Total current assets | 254,988 | 288,266 |
| Property and equipment, net | 12,274 | 9,938 |
| Other assets | 3,228 | 381 |
| Total assets | $ 270,490 | $ 298,585 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,593 | $ 10,012 |
| Accrued expenses and other current liabilities | 14,221 | 14,574 |
| Total current liabilities | 16,814 | 24,586 |
| Non-current operating lease liabilities | 4,738 | |
| Deferred rent | — | 2,213 |
| Total liabilities | 21,552 | 26,799 |
| Stockholders' equity: | | |
| Common stock | 5 | 5 |
| Additional paid-in capital | 391,055 | 389,408 |
| Accumulated other comprehensive loss | (527) | (560) |
| Accumulated deficit | (141,595) | (117,067) |
| Total stockholders' equity | 248,938 | 271,786 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 270,490 | $ 298,585 |

**SHATTUCK LABS, INC.**
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(Unaudited)**

**(In thousands, except share and per share amounts)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Collaboration revenue - related party | $ — | $ 2,270 |
| Operating expenses: | | |
| Research and development | 19,187 | 10,337 |
| General and administrative | 4,979 | 4,356 |
| Expense from operations | 24,166 | 14,693 |
| Loss from operations | (24,166) | (12,423) |
| Other income (expense): | | |
| Other | (362) | 610 |
| Net loss | $ (24,528) | $ (11,813) |
| Unrealized gain (loss) on investments | 33 | (597) |
| Comprehensive loss | $ (24,495) | $ (12,410) |
| Net loss per share – basic and diluted | $ (0.58) | $ (0.28) |
| Weighted-average shares outstanding – basic and diluted | 42,357,625 | 41,774,111 |

Source: Shattuck Labs, Inc.