



# Shattuck Labs Reports First Quarter 2023 Financial Results and Recent Business Highlights

2023-05-09

*— Complete data from Phase 1A clinical trial of SL-172154 as monotherapy in platinum-resistant ovarian cancer (PROC) to be presented at the 2023 American Society of Clinical Oncology (ASCO) annual meeting in June –*

*— Dosed first patients in Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC, initial data expected in the second half of 2023 –*

*— Enrollment in dose-escalation portion of the Phase 1A/B clinical trial of SL-172154 in acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (HR-MDS) expected to be complete in the second quarter; complete dose escalation and initial frontline expansion cohort data expected in the second half of 2023 –*

*— Initial data from the Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in PROC expected midyear 2023 –*

AUSTIN, TX and DURHAM, NC, May 09, 2023 (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, 2023, and provided recent business highlights.

"As a result of steady clinical progress through the first quarter of 2023, key efficacy readouts from our ongoing clinical trials for SL-172154 in PROC and AML/HR-MDS are expected midyear and in the second half of 2023, respectively. Additionally, our poster presentation at ASCO next month will provide further context for our selection of 3 mg/kg which we believe to be the optimal dose to move into combination trials with liposomal doxorubicin in patients with PROC. We are further encouraged by ImmunoGen's positive Phase 3 confirmatory MIRASOL trial last week, and our clinical trial of SL-172154 in combination with mirvetuximab soravtansine is also proceeding nicely," commented Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. "I am also pleased to report that the dose-escalation portion of our Phase 1 trial in AML/HR-MDS has enrolled very well, and we expect to complete enrollment in that portion of the study in the second quarter. We then plan to proceed

immediately to the frontline expansion cohorts in HR-MDS and TP53 mutant AML and to share initial data from those cohorts in the second half of the year. We expect that the data both from the dose-escalation and expansion portions of this trial will help inform what benefit SL-172154 may provide beyond azacitidine alone.”

## **Anticipated Milestones**

### ***ARC Platform***

SL-172154 (SIRP $\alpha$ -Fc-CD40L)

- Complete data from Phase 1A dose-escalation clinical trial of SL-172154 as monotherapy in PROC to be presented at the 2023 ASCO annual meeting
- Initial data from Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in PROC expected midyear 2023
- Complete dose-escalation data, as monotherapy and in combination with azacitidine, for Phase 1A/B clinical trial of SL-172154 in AML and HR-MDS and initial dose-expansion cohort data of SL-172154 in combination with azacitidine in frontline TP53 mutant AML or HR-MDS cohorts expected in the second half of 2023
- Initial data from Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC expected in the second half of 2023

### ***GADLEN Platform***

GADLEN Preclinical Compounds

- Additional clinical development detail and further program guidance regarding the advancement of potential product candidates from the GADLEN platform expected in 2023

## **First Quarter 2023 Recent Business Highlights and Other Recent Developments**

### ***ARC Clinical-Stage Pipeline***

SL-172154 (SIRP $\alpha$ -Fc-CD40L)

- **Presenting Complete Dose-Escalation Data from Phase 1A Monotherapy Clinical Trial of SL-172154 in PROC at 2023 ASCO Annual Meeting:** This open-label, multi-center, dose-escalation clinical trial evaluated the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 administered intravenously in patients with PROC. Dose escalation reached a maximum administered dose of 10 mg/kg.
- **Enrollment Progressing in Ongoing Phase 1A/B Clinical Trial in AML and HR-MDS:** This trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 as both monotherapy and in combination. In the dose-escalation portion of this trial, enrollment is complete in the monotherapy cohorts through 6 mg/kg, and in the combination cohorts, in combination with azacitidine, through 3 mg/kg. To date, SL-172154, both alone and in combination, has an acceptable safety profile. The final dose-escalation cohort of SL-172154 at 6 mg/kg in combination with azacitidine is expected to complete enrollment in the second quarter. The trial will then evaluate SL-172154 in combination with azacitidine in an expansion cohort in frontline HR-MDS patients and a second expansion cohort in frontline TP53 mutant AML patients. Both expansion cohorts are expected to begin enrollment in the third quarter of 2023, and we now expect to complete enrollment in both expansion cohorts during the second half of 2023. We expect to share full dose-escalation data and initial data from the

frontline expansion cohorts in the second half of 2023.

- **Enrollment Progressing in Phase 1B Clinical Trial of SL-172154 in Combination with Liposomal Doxorubicin in PROC:** Enrollment is continuing in this trial, which is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154, using the selected dose of 3 mg/kg, in combination with liposomal doxorubicin in patients with PROC. We expect to present initial data from the trial midyear 2023.
- **Dosed First Patients in Phase 1B Clinical Trial of SL-172154 in Combination with Mirvetuximab Soravtansine in PROC.** This trial is evaluating the safety, pharmacokinetics, pharmacodynamic effects, and preliminary anti-tumor activity of SL-172154 administered in combination with mirvetuximab soravtansine in patients with PROC. Mirvetuximab soravtansine is an antibody-drug conjugate targeting folate receptor alpha (FR $\alpha$ ), which provides for both direct tumor cell killing as well as enhanced macrophage phagocytosis through binding with Fc gamma receptors and has received accelerated approval for PROC patients whose tumors are shown to be FR $\alpha$  positive, defined as  $\geq 75\%$ , as determined by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. Preclinical studies have shown that both of these killing mechanisms are complementary to the mechanism of SL-172154 by enhancing the activity of macrophages to phagocytose FR $\alpha$ -expressing ovarian cancer cells, and that SL-172154 may broaden the activity of mirvetuximab, particularly in patients with tumors that express lower levels of FR $\alpha$ . We intend to enroll patients with broader FR $\alpha$  expression, including those with “high” (greater than  $\geq 75\%$ ), “medium” ( $\geq 50\%$  to  $< 75\%$ ), and “low” ( $\geq 25\%$  to  $< 50\%$ ) expression of FR $\alpha$ , as determined by the VENTANA FOLR1 (FOLR1-2.1). We expect to present initial data from the trial in the second half of 2023.

### ***Gamma Delta T Cell Engager (GADLEN) Preclinical Pipeline***

#### Preclinical Pipeline Development

- We presented preclinical data from our GADLEN platform at the American Association for Cancer Research (AACR) annual meeting in April 2023 that demonstrated that the CD20-targeted GADLEN efficiently directs small numbers of human V $\gamma 9\text{V}\delta 2$  T cells to serially kill greater than 99% of human B cells in a humanized mouse model. These results led to the first study of a GADLEN compound in non-human primates, where once again treatment with a CD20-targeted GADLEN directed low frequencies of endogenous V $\gamma 9\text{V}\delta 2$  T cells to eliminate CD20 positive B cells with a rapid kinetic. The GADLEN compound was well tolerated in non-human primates up to the highest administered dose of 25 mg/kg, without evidence of cytokine release syndrome or other toxicities, potentially providing differentiation from CD3-directed T cell engagers.

#### **First-Quarter 2023 Financial Results**

- **Cash and Cash Equivalents and Investments:** As of March 31, 2023, cash and cash equivalents and investments were \$135.5 million, as compared to \$239.2 million as of March 31, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were \$16.7 million for the quarter ended March 31, 2023, as compared to \$19.2 million for the quarter ended March 31, 2022. This decrease was primarily driven by a decrease in expense associated with the manufacture of clinical trial materials to support our ongoing clinical trials.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$5.1 million for the quarter ended March 31, 2023, as compared to \$5.0 million for the quarter ended March 31, 2022.
- **Net Loss:** Net loss was \$20.7 million for the quarter ended March 31, 2023, or \$0.49 per basic and diluted share, as compared to a net loss of \$24.5 million for the quarter ended March 31, 2022, or \$0.58 per basic and diluted share.

#### **2023 Financial Guidance**

Shattuck believes its cash and cash equivalents and investments will be sufficient to fund its operations through year-end 2024, beyond results from its Phase 1 clinical trials of SL-172154. This cash runway guidance is based on the Company's current operational plans and excludes any additional capital that may be received, proceeds from business development transactions, and/or additional costs associated with clinical development activities that may be undertaken.

### **About SL-172154**

SL-172154 (SIRP $\alpha$ -Fc-CD40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the CD47/SIRP $\alpha$  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 PROC (NCT04406623, NCT05483933) and patients with AML and HR-MDS (NCT05275439).

### **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 lead SL-172154 (SIRP $\alpha$ -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. 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](http://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, plans for clinical trial design, 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: global macroeconomic conditions and related volatility, 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, 2022, 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.  
 CONDENSED BALANCE SHEETS**

(In thousands)

	<b>March 31, 2023 (unaudited)</b>	<b>December 31, 2022</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 66,043	\$ 47,379
Investments	69,452	113,901
Prepaid expenses and other current assets	22,342	23,304
Total current assets	<u>157,837</u>	<u>184,584</u>
Property and equipment, net	16,887	17,671
Other assets	2,953	3,069
Total assets	<u>\$ 177,677</u>	<u>\$ 205,324</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,128	\$ 7,170
Accrued expenses and other current liabilities	10,881	17,795
Total current liabilities	<u>16,009</u>	<u>24,965</u>
Non-current operating lease liabilities	4,014	4,202
Total liabilities	<u>20,023</u>	<u>29,167</u>
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	397,724	396,041
Accumulated other comprehensive loss	(339)	(877)
Accumulated deficit	<u>(239,736)</u>	<u>(219,012)</u>
Total stockholders' equity	<u>157,654</u>	<u>176,157</u>
Total liabilities and stockholders' equity	<u>\$ 177,677</u>	<u>\$ 205,324</u>

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

(In thousands, except share and per share amounts)

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Collaboration revenue	\$ 57	\$ —
Operating expenses:		
Research and development	16,667	19,187
General and administrative	5,051	4,979
Expense from operations	<u>21,718</u>	<u>24,166</u>
Loss from operations	(21,661)	(24,166)
Other income (expense)	937	(362)
Net loss	<u>\$ (20,724)</u>	<u>\$ (24,528)</u>
Unrealized gain on investments	538	33
Comprehensive loss	<u>\$ (20,186)</u>	<u>\$ (24,495)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.58)</u>
Weighted-average shares outstanding - basic and diluted	42,439,204	42,357,625

Source: Shattuck Labs, Inc.