



# Shattuck Labs Reports First Quarter 2024 Financial Results and Recent Business Highlights

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*- Completed additional enrollment in Phase 1B dose-expansion cohorts for TP53 mutant (TP53m) Acute Myeloid Leukemia (AML) patients in the first quarter of 2024; updated combination data expected at the European Society of Hematology (EHA) 2024 Annual Meeting in June –*

*- Randomized, controlled Phase 1B dose-expansion cohort in frontline Higher-Risk Myelodysplastic Syndromes (HR-MDS) patients expected to initiate enrollment in the second quarter of 2024 –*

*- Presented preclinical data at the 2024 American Association for Cancer Research (AACR) Annual Meeting, demonstrating the potential therapeutic utility of TRIM7 inhibition to prevent or reverse acquired resistance to immune checkpoint therapy –*

AUSTIN, TX and DURHAM, NC., May 02, 2024 (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, 2024 and provided recent business highlights.

"We were pleased to see rapid enrollment to the expanded TP53m AML cohort in January. We also expect to see similarly rapid enrollment through the remainder of 2024 into the randomized and controlled expansion cohort in frontline HR-MDS patients," said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. "We remain excited about the profile of SL-172154 in frontline AML and HR-MDS and are looking forward to sharing additional response and initial survival data in June. In addition to our clinical momentum, we have continued to advance our pre-clinical pipeline to create additional opportunities for growth and value alongside SL-172154. Our collaboration with Ono Pharma on compounds outside of oncology, and our recent oral presentation on a novel small molecule inhibitor of TRIM7 as a potential means to prevent and address acquired resistance to checkpoint inhibitors, are the first two examples of that strategy."

## **Clinical Milestones Expected in 2024**

## **SL-172154 (SIRPα-Fc-CD40L)**

- Objective response rates and duration of response based on the then-available data from the Phase 1B expansion cohorts of SL-172154 in combination with azacitidine (AZA) in frontline HR-MDS and frontline TP53m AML expected at the EHA 2024 Annual Meeting in June.
- Randomized, controlled Phase 1B dose-expansion cohort in frontline HR-MDS patients is expected to initiate enrollment in the second quarter of 2024. Approximately 60 patients will be randomized in a 1:1:1 ratio to receive SL-17254 at 3mg/kg in combination with AZA, SL-17254 at 1mg/kg in combination with AZA, or AZA as a monotherapy.
- Objective response rate and duration of response data based on the then-available data from the Phase 1B clinical trial of SL-172154 in combination with pegylated liposomal doxorubicin (PLD) in Platinum-Resistant Ovarian Cancer (PROC) expected mid-year 2024.
- Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC expected to complete enrollment in the second quarter of 2024, followed by initial data expected mid-year 2024.

## **First Quarter 2024 Business Highlights and Other Recent Developments**

### **Preclinical**

- **Presented preclinical data at the 2024 AACR Annual Meeting:** Demonstrated the potential therapeutic utility of TRIM7 inhibition to prevent or reverse acquired resistance to immune checkpoint therapy. These data were featured in an oral presentation during the 2024 AACR Annual Meeting.
  - Results build on a recent publication in the journal *Cancer Cell*, where Shattuck's preclinical anti-PD1 acquired resistance mouse model helped to elucidate the underlying biology of acquired resistance and identify a novel target, TRIM7. Shattuck expects that these efforts will support expansion of its oncology pipeline alongside lead program, SL-172154.
- **Shattuck and Ono Enter into Collaboration Agreement:** On February 13, 2024, Shattuck announced a strategic collaboration and license agreement with Ono Pharmaceutical Co., Ltd. (Ono) in which Shattuck will lead the research and preclinical development of certain compounds selected by Ono from its pipeline of bifunctional fusion proteins to a pair of prespecified targets for potential treatment of autoimmune and inflammatory diseases.

### **Corporate Updates**

- **Shattuck Appoints Clay Siegall, Ph.D., and Kate Sasser, Ph.D., to its Board of Directors:** On March 4, 2024, Shattuck announced the appointment of Clay Siegall, Ph.D. and Kate Sasser, Ph.D. to its Board of Directors, effective March 1, 2024. Both Dr. Siegall and Dr. Sasser are highly successful executives and scientific pioneers who bring valuable industry experience to Shattuck.

## **First Quarter 2024 Financial Results**

- **Cash and Cash Equivalents and Investments:** As of March 31, 2024, cash and cash equivalents and investments were \$114.6 million, as compared to \$135.5 million as of March 31, 2023.
- **Research and Development (R&D) Expenses:** R&D expenses were \$16.3 million for the quarter ended March 31, 2024, as compared to \$16.7 million for the quarter ended March 31, 2023.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$4.9 million for the quarter ended March 31, 2024, as compared to \$5.1 million for the quarter ended March 31, 2023.
- **Net Loss:** Net loss was \$18.5 million for the quarter ended March 31, 2024, or \$0.37 per basic and diluted share, as compared to a net loss of \$20.7 million for the quarter ended March 31, 2023, or \$0.49 per basic and diluted share.

## Financial Guidance

Shattuck believes its cash and cash equivalents and investments will be sufficient to fund its operations into 2026, 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<sup>®</sup> 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 and patients with AML and HR-MDS:

- **Ongoing Phase 1A/B Clinical Trial of SL-172154 in Frontline HR-MDS and Frontline TP53m AML Patients:** This trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 in combination with AZA in both frontline HR-MDS patients and frontline TP53m AML patients. A randomized cohort in frontline HR-MDS patients is expected to initiate enrollment in the second quarter of 2024. Approximately 60 patients will be randomized in a 1:1:1 ratio to receive SL-172154 at 3mg/kg in combination with AZA, SL-172154 at 1mg/kg in combination with AZA, or AZA as a monotherapy.
- **Ongoing Phase 1B Clinical Trial of SL-172154 in Combination with PLD in PROC Patients:** This trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 at 3.0 mg/kg in combination with PLD in patients with PROC. The initial data from this Phase 1B clinical trial in PROC patients was presented in November 2023. Initial data suggest that SL-172154 improved the response rate relative to what would be expected from PLD alone, and SL-172154 had an acceptable safety profile in combination with PLD. Objective response rate and duration of response based on the then-available data from the Phase 1B clinical trial of SL-172154 in combination with PLD in PROC are expected mid-year 2024.
- **Ongoing Phase 1B Clinical Trial of SL-172154 in Combination with Mirvetuximab Soravtansine in PROC Patients:** 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 in the United States 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) Assay. Enrollment completion for the Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC is expected in the second quarter of 2024, followed by initial data expected mid-year 2024.

## 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<sup>®</sup>), platform are designed to 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. 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 expansion of clinical trials; the anticipated timing of the results from our clinical trials; the anticipated timing and pace of enrollment in our clinical trials; the clinical benefit, safety and tolerability of SL-172154; the potential therapeutic utility of TRIM7 inhibition to prevent or reverse acquired resistance to immune checkpoint therapy; 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 (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, 2023, 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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**SHATTUCK LABS, INC.  
CONDENSED BALANCE SHEETS**

(In thousands)

	<b>March 31, 2024 (unaudited)</b>	<b>December 31, 2023</b>
<b>Assets</b>		
Current assets:		

Cash and cash equivalents	\$	76,005	\$	125,626
Investments		38,628		4,999
Prepaid expenses and other current assets		16,443		12,595
Total current assets		<u>131,076</u>		<u>143,220</u>
Property and equipment, net		12,830		13,804
Other assets		2,429		2,540
Total assets	\$	<u>146,335</u>	\$	<u>159,564</u>

### Liabilities and Stockholders' Equity

Current liabilities:				
Accounts payable	\$	2,154	\$	1,587
Accrued expenses and other current liabilities		7,569		9,523
Deferred revenue		4,606		343
Total current liabilities		<u>14,329</u>		<u>11,453</u>
Non-current operating lease liabilities		3,193		3,406
Total liabilities		<u>17,522</u>		<u>14,859</u>
Stockholders' equity:				
Common stock		5		5
Additional paid-in capital		453,636		451,006
Accumulated other comprehensive (loss) income		(14)		4
Accumulated deficit		<u>(324,814)</u>		<u>(306,310)</u>
Total stockholders' equity		<u>128,813</u>		<u>144,705</u>
Total liabilities and stockholders' equity	\$	<u>146,335</u>	\$	<u>159,564</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>2024</b>	<b>2023</b>
Collaboration revenue	\$ 1,115	\$ 57
Operating expenses:		
Research and development	16,264	16,667
General and administrative	4,895	5,051
Expense from operations	<u>21,159</u>	<u>21,718</u>
Loss from operations	(20,044)	(21,661)
Other income	1,540	937
Net loss	<u>\$ (18,504)</u>	<u>\$ (20,724)</u>
Unrealized (loss) gain on investments	(18)	538
Comprehensive loss	<u>\$ (18,522)</u>	<u>\$ (20,724)</u>
Net loss per share – basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.49)</u>
Weighted-average shares outstanding – basic and diluted	50,566,394	42,439,204

Source: Shattuck Labs, Inc.