



# Shattuck Labs Reports Fourth Quarter and Full-Year 2023 Financial Results and Recent Business Highlights

2024-02-29

- *Announced positive topline data from the ongoing Phase 1A/B clinical trial of SL-172154 in combination with azacitidine (AZA) in frontline Higher-Risk Myelodysplastic Syndromes (HR-MDS) and frontline TP53 mutant (TP53m) Acute Myeloid Leukemia (AML) patients; initial data build on the dose-escalation data featured in a poster presentation at the American Society of Hematology (ASH) Annual Meeting –*
- *Completed initial enrollment in Phase 1B dose-expansion cohorts for frontline HR-MDS and TP53m AML patients in the fourth quarter of 2023; additional enrollment ongoing, with updated combination data expected mid-year 2024 –*
- *Completed enrollment and presented positive interim data from the Phase 1B clinical trial of SL-172154 in combination with pegylated liposomal doxorubicin (PLD) in platinum-resistant ovarian cancer (PROC), which demonstrated an acceptable safety profile and encouraging anti-tumor activity that compares favorably to PLD as a monotherapy –*
- *Entered into strategic collaboration and license agreement with Ono Pharmaceutical Co., Ltd (Ono) to generate novel bifunctional fusion proteins with the potential to treat autoimmune and inflammatory diseases –*
- *Completed \$50 million offering of common stock and pre-funded warrants in the fourth quarter of 2023, extending cash runway into 2026 –*

AUSTIN, TX and DURHAM, NC, Feb. 29, 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 fourth quarter and full year ended December 31, 2023 and provided recent business highlights.

“Over the course of 2023, the SL-172154 program rapidly transitioned from Phase 1A dose-escalation

studies to Phase 1B dose-expansion studies in PROC, HR-MDS, and TP53m AML, which enabled us to share initial efficacy data in the fourth quarter,” said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. “We have now begun 2024 with the momentum and financial resources to expand our HR-MDS and TP53m AML studies and capitalize on the potential first-in-class opportunity that now exists in those indications. We have expanded our ongoing trials, and look forward to defining our registrational strategy following the next clinical updates expected mid-year in HR-MDS, AML, and PROC. While we will remain focused on advancing SL-172154, our pre-clinical pipeline has continued to mature, as evidenced by our recent collaboration with Ono, and publications in both *Cancer Cell* and *Cancer Research*. We look forward to providing additional updates across the portfolio over the course of 2024.”

## Clinical Milestones Expected in 2024

### **SL-172154 (SIRP $\alpha$ -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 AZA in frontline HR-MDS and frontline TP53m AML expected mid-year 2024.
- 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 expected mid-year 2024.
- Initial combination data from the Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC expected mid-year 2024.

## Fourth Quarter 2023 Business Highlights and Other Recent Developments

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

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

- **Completed Initial Enrollment and Expanded the Phase 1B Portion of the 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. The data from the dose-escalation portion of the clinical trial in primarily relapsed/refractory patients was presented at the 65<sup>th</sup> ASH Annual Meeting. Initial data from the dose-expansion portion of the trial in frontline patients suggest that SL-172154 improved complete response rates relative to what would be expected historically with AZA alone in previously untreated HR-MDS (predominantly TP53m HR-MDS population) and TP53m AML. SL-172154 demonstrated an acceptable safety and tolerability profile both as monotherapy and in combination with AZA. No destructive anemia was observed. 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 AZA in frontline HR-MDS and TP53m AML are expected mid-year 2024.
- **Completed Enrollment of Ongoing Phase 1B Clinical Trial of SL-172154 in Combination with PLD in PROC Patients and Presented Positive Interim Data:** This trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 (using the selected dose of 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. The initial data suggest 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.

- **Continued Dosing in 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. Initial combination data from the Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC is expected mid-year 2024.

### **Preclinical**

- **Published Acquired Resistance (AR) Model in *Cancer Cell*:** In a recent publication in the journal *Cancer Cell*, the preclinical development of a mouse anti-PD1 AR model by Shattuck was shown to closely mimic the clinical and molecular signatures of those in human patients with non-small cell lung cancer (NSCLC), who have developed AR to anti-PD(L)1 therapies, including a dysregulated interferon response. Findings such as these are important to guide the identification of new targets and development of new treatment strategies for this growing unmet need.
- **Published Preclinical mRNA Work in *Cancer Research*:** In a recent study published in *Cancer Research*, scientists at Shattuck and Moderna demonstrated the feasibility of delivering certain hexameric, dual-sided fusion proteins as lipid-encapsulated mRNA. The expression level, duration of exposure, and efficacy in a murine anti-tumor model achieved by the mRNA delivery outperformed that of the corresponding intravenous administration of recombinant fusion proteins. These results demonstrated feasibility for delivery of complex fusion proteins generally, which may have important pharmacokinetic and pharmacoeconomic benefits for indications outside of oncology.

### **Upcoming Events**

- **Shattuck plans to attend the following investor or scientific conferences.** Details are included on the [Events & Presentations](#) section of the Company's website.
  - Cowen 44th Annual Health Care Conference (Boston, MA) March 4-6, 2024
  - Leerink Global Biopharma Conference (Miami, FL) March 11-13, 2024
  - Citi's Biotech C-Suite Fireside Chat Series, held virtually March 20, 2024
  - American Association of Cancer Research Annual Meeting (San Diego, CA) April 5-10, 2024

### **Corporate Updates**

- **Shattuck and Ono Enter into Collaboration Agreement:** On February 13, 2024, Shattuck announced a strategic collaboration and license agreement with Ono in which Shattuck will lead 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. Under the terms of the agreement, Shattuck will receive an up-front payment and be eligible for success-based licensing, regulatory, and commercial milestone payments with a total value of up to \$227 million, as well as tiered royalties based on global net sales. Shattuck will lead discovery research of certain prespecified compounds.
- **Shattuck Closes Financing:** On December 21, 2023, Shattuck announced a \$50 million public

offering of common stock and concurrent private placement of pre-funded warrants. Net proceeds from the public offering and the private placement are intended to further support the development of its pipeline candidates, including SL-172154, as well as general working capital.

#### **Fourth Quarter and Full-Year 2023 Financial Results**

- **Cash and Cash Equivalents and Investments:** As of December 31, 2023 cash and cash equivalents and investments were \$130.6 million, as compared to \$161.3 million as of December 31, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended December 31, 2023, were \$15.2 million, as compared to \$21.9 million for the quarter ended December 31, 2022. R&D expenses for the year ended December 31, 2023 were \$74.3 million, as compared to \$82.9 million for the year ended December 31, 2022. This decrease was primarily driven by decreases in the manufacturing of trial materials to support clinical development of our ongoing clinical trials, personnel-related costs, and lab supplies but were offset by an increase in clinical trial cost.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended December 31, 2023 were \$4.4 million, as compared to \$4.8 million for the quarter ended December 31, 2022. General and administrative expenses for the year ended December 31, 2023 were \$19.3 million, as compared to \$21.1 million for the year ended December 31, 2022. This decrease for the full year was primarily the result of recognizing a litigation settlement of \$1.4 million in 2022, and the decrease in the fourth quarter of 2023 was primarily driven by a decrease in insurance and personnel-related cost.
- **Net Loss:** Net loss was \$17.7 million for the quarter ended December 31, 2023, or \$0.41 per basic and diluted share, as compared to a net loss of \$25.4 million for the quarter ended December 31, 2022, or \$0.60 per basic share and diluted share. Net loss for the year ended December 31, 2023 was \$87.3 million, or \$2.05 per basic and diluted share, as compared to \$101.9 million, or \$2.41 per basic and diluted share, for the year ended December 31, 2022.

#### **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.

#### **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 clinical benefit, safety and tolerability of SL-172154, 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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## FINANCIAL INFORMATION

### SHATTUCK LABS, INC. BALANCE SHEETS

(In thousands)

December 31,

	<u>2023</u>	<u>2022</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 125,626	\$ 47,379
Investments	4,999	113,901
Prepaid expenses and other current assets	12,595	23,304
Total current assets	<u>143,220</u>	<u>184,584</u>
Property and equipment, net	13,804	17,671
Other assets	2,540	3,069
Total assets	<u>\$ 159,564</u>	<u>\$ 205,324</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,587	\$ 7,170
Accrued expenses and other current liabilities	9,866	17,795
Total current liabilities	<u>11,453</u>	<u>24,965</u>
Non-current operating lease liabilities	3,406	4,202
Total liabilities	<u>14,859</u>	<u>29,167</u>
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	451,006	396,041
Accumulated other comprehensive income (loss)	4	(877)
Accumulated deficit	<u>(306,310)</u>	<u>(219,012)</u>
Total stockholders' equity	<u>144,705</u>	<u>176,157</u>
Total liabilities and stockholders' equity	<u>\$ 159,564</u>	<u>\$ 205,324</u>

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

	<b>Three Months Ended</b>		<b>Year Ended December 31,</b>	
	<b>December 31,</b>		<b>2023</b>	
	<b>(Unaudited)</b>		<b>2022</b>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Collaboration revenue	\$ 714	\$ 390	\$ 1,657	\$ 652
Operating expenses:				
Research and development	15,227	21,887	74,310	82,899
General and administrative	4,438	4,779	19,304	21,082
Expense from operations	<u>19,665</u>	<u>26,666</u>	<u>93,614</u>	<u>103,981</u>
Gain (loss) from operations	<u>(18,951)</u>	<u>(26,276)</u>	<u>(91,957)</u>	<u>(103,329)</u>
Other income (expense):				
Interest income (expense)	1,268	908	4,669	1,592
Other	<u>(4)</u>	<u>(43)</u>	<u>(10)</u>	<u>(208)</u>
Total other income (expense)	<u>1,264</u>	<u>865</u>	<u>4,659</u>	<u>1,384</u>
Net income (loss)	<u>\$ (17,687)</u>	<u>\$ (25,411)</u>	<u>\$ (87,298)</u>	<u>\$ (101,945)</u>
Unrealized gain (loss) on investments	<u>(3)</u>	<u>\$ 457</u>	<u>881</u>	<u>(317)</u>
Comprehensive gain (loss)	<u>\$ (17,690)</u>	<u>\$ (24,954)</u>	<u>\$ (86,417)</u>	<u>\$ (102,262)</u>

Basic and Diluted Per Common Share  
Data:

Net earnings (loss) per share - basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.60)</u>	<u>\$ (2.05)</u>	<u>\$ (2.41)</u>
Weighted-average shares outstanding - basic and diluted	43,011,310	42,390,586	42,600,190	42,378,895

Source: Shattuck Labs, Inc.