



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

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- Announced updated positive interim data from the Phase 1B dose-expansion clinical trial of SL-172154 in combination with Azacitidine (AZA) in frontline Higher-Risk Myelodysplastic Syndromes (HR-MDS) and TP53 mutant (TP53m) Acute Myeloid Leukemia (AML) patients at the European Society of Hematology (EHA) 2024 Annual Meeting -*
- Enrollment ongoing in the randomized, controlled Phase 1B dose-expansion cohort in frontline HR-MDS patients -*
- Announced Orphan Drug Designation (ODD) granted by the U.S. Food and Drug Administration (FDA) for SL-172154 for the treatment of AML-*

AUSTIN, TX and DURHAM, NC, Aug. 01, 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 June 30, 2024 and provided recent business highlights.

"Our data presentation at EHA last quarter included complete remission rates for both HR-MDS and TP53m AML patients treated with SL-172154 in combination with AZA that exceeded the expected complete remission rates for AZA alone. It is encouraging to see in our EHA presentation that our complete remission rate improved as the number of patients in each cohort increased, since our initial data presented at ASH in December of 2023. The next milestone for this program is to see how these response rates translate to an overall survival benefit, and those data will mature over the second half of this year," said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. "In parallel, we are pleased that enrollment has begun so swiftly in our randomized, controlled expansion cohort in frontline HR-MDS patients. We look forward to sharing clinical updates from these trials in the months ahead."

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

## *SL-172154 (SIRPα-Fc-CD40L)*

### *Phase 1B Trial of SL-172154 in Frontline HR-MDS and TP53m AML*

#### **HR-MDS**

- Announced updated interim data from the Phase 1B dose expansion clinical trial of SL-172154 in combination with AZA in frontline HR-MDS and TP53m AML patients. These data were featured in a poster presentation during the EHA 2024 Congress.
  - Observed 67% Objective Response Rate (ORR) in frontline HR-MDS patients, primarily with TP53 mutations, and an initial complete remission (CR)/marrow complete remission rate of 58%. As of the data cut-off date on April 23, 2024, median overall survival had not yet been reached.
  - SL-172154 demonstrated a manageable interim safety profile in combination with AZA, with infusion related reactions (IRRs) as the most common drug related adverse event.
- Initiated enrollment of the Part D cohort, a randomized, controlled Phase 1B dose-expansion cohort in frontline HR-MDS patients. 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 monotherapy.

#### **TP53m AML**

- Observed 43% ORR in frontline TP53m AML patients and 33% CR/complete remission rate with incomplete hematologic recovery. As of the data cut-off date of June 4, 2024, the median overall survival had not yet been reached. SL-172154 demonstrated a manageable interim safety profile in combination with AZA.
- In June 2024, the U.S. FDA granted ODD to SL-172154 for the treatment of AML.

### *Phase 1B Trial of SL-172154 in Platinum-Resistant Ovarian Cancer (PROC)*

- Reported data from the Phase 1B clinical trial of SL-172154 in PROC patients, demonstrating an acceptable safety profile in combination with pegylated liposomal doxorubicin (PLD) or mirvetuximab soravtansine (Elahere). IRRs were the most common treatment emergent AE as of the data cutoff.
  - As of April 23, 2024, four of 21 (19%) treated patients in the Phase 1B study of SL-172154 in combination with PLD achieved partial responses. Two additional patients with stable disease showed maximum tumor reductions of 17% and 27%.
  - Completed enrollment for the cohort combining SL-172154 with Elahere. As of the April 23, 2024 data cutoff, ORR benefit beyond Elahere alone was not observed.
  - Shattuck continues to follow patients for progression free survival and overall survival and, should such results mature favorably in either PROC cohort, will evaluate further development in PROC at that time.

#### *Corporate Updates*

- On July 1, 2024, Shattuck announced its addition to the Russell 2000® and Russell 3000® Indexes at the conclusion of the 2024 Russell U.S. Indexes annual reconstitution.

#### **Upcoming Events**

- **Shattuck plans to attend the following investor conferences. Details will be included on the [Events & Presentations](#) section of the Company's website.**
  - BTIG Biotechnology Conference (Virtual) August 5-6, 2024
  - Wells Fargo Healthcare Conference (Boston, MA) September 4-6, 2024
  - H.C. Wainwright 26th Annual Global Investment Conference (New York, NY) September 9-11, 2024

## Second Quarter 2024 Financial Results

- **Cash and Cash Equivalents and Investments:** As of June 30, 2024, cash and cash equivalents and investments were \$105.3 million, as compared to \$117.2 million as of June 30, 2023.
- **Research and Development (R&D) Expenses:** R&D expenses were \$19.2 million for the quarter ended June 30, 2024, as compared to \$18.2 million for the quarter ended June 30, 2023.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$5.3 million for the quarter ended June 30, 2024, as compared to \$4.7 million for the quarter ended June 30, 2023.
- **Net Loss:** Net loss was \$21.5 million for the quarter ended June 30, 2024, or \$0.42 per basic and diluted share, as compared to a net loss of \$21.3 million for the quarter ended June 30, 2023, or \$0.50 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 AML, HR-MDS, and PROC.

## 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



Accounts payable	\$	2,822		1,587
Deferred revenue		2,997		343
Total current liabilities		15,026		11,453
Non-current operating lease liabilities		2,972		3,406
Total liabilities	\$	17,998	\$	14,859
Stockholders' equity:				
Common stock		5		5
Additional paid in capital		456,982		451,006
Accumulated other comprehensive (loss) income		(5)		4
Accumulated deficit		(346,366)		(306,310)
Total stockholders' equity		110,616		144,705
Total liabilities and stockholders' equity	\$	128,614	\$	159,564

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

	<b>Three Months Ended June</b>		<b>Six Months Ended June 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Collaboration revenue	\$ 1,609	\$ 200	\$ 2,724	\$ 257
Operating expenses:				
Research and development	19,239	18,205	35,503	34,872
General and administrative	5,332	4,742	10,227	9,793
Expense from operations	24,571	22,947	45,730	44,665
Loss from operations	(22,962)	(22,747)	(43,006)	(44,408)
Other income	1,410	1,401	2,950	2,338
Net loss	\$ (21,552)	\$ (21,346)	\$ (40,056)	\$ (42,070)
Unrealized gain (loss) on investments	9	265	(9)	803
Comprehensive loss	\$ (21,543)	\$ (21,081)	\$ (40,065)	\$ (41,267)
Net loss per share - basic and diluted	\$ (0.42)	\$ (0.50)	\$ (0.79)	\$ (0.99)
Weighted-average shares outstanding - basic and diluted	50,791,241	42,467,664	50,678,818	42,453,513

Source: Shattuck Labs, Inc.