



Shattuck Labs Reports Second Quarter 2023 Financial Results and Recent Business Highlights

2023-08-10

- Presented complete data from Phase 1A clinical trial of SL-172154 as monotherapy in platinum-resistant ovarian cancer (PROC) at the American Society of Clinical Oncology (ASCO) 2023 annual meeting, including data supporting 3 mg/kg as the appropriate dose for each PROC combination cohort -*
- Completed enrollment in the dose-escalation portion of the Phase 1A/B clinical trial of SL-172154 in relapsed/refractory acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (HR-MDS); and expect to complete enrollment in both frontline expansion cohorts in HR-MDS and TP53 mutant AML in the fourth quarter of 2023 -*
- Enrollment progressing in the Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in PROC, completion of enrollment and initial data expected in the fourth quarter of 2023 -*
- Enrollment progressing in the Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC; initial data expected in the fourth quarter of 2023 -*

AUSTIN, TX and DURHAM, NC, Aug. 10, 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 June 30, 2023, and provided recent business highlights.

"We are pleased with our continued progress in enrollment in our ongoing trials in the second quarter of 2023, and in particular to now have four different expansion cohorts well underway in our AML/HR-MDS and PROC trials," said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. "We believe that data from our dose-escalation study in PROC presented at ASCO demonstrated that SL-172154 may be a differentiated CD47 inhibitor due to the integrated CD40 agonist function, and we look forward to sharing initial combination data across multiple tumors and lines of therapy by the end of the year."

2023 Anticipated Milestones

ARC Platform

SL-172154 (SIRP α -Fc-CD40L)

- Complete enrollment and initial data from the ongoing Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in PROC expected in the fourth quarter of 2023.
- Initial data from the ongoing Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in PROC expected in the fourth quarter of 2023.
- Complete dose-escalation data, as monotherapy and in combination with azacitidine, for Phase 1A clinical trial of SL-172154 in primarily relapsed/refractory AML and HR-MDS expected in the fourth quarter of 2023.
- Completion of enrollment in the frontline TP53 mutant AML dose-expansion cohort and frontline HR-MDS dose-expansion cohort from our ongoing Phase 1A/B clinical trial of SL-172154 and initial data expected in the fourth quarter of 2023.

Second Quarter 2023 Recent Business Highlights and Other Recent Developments

ARC Clinical-Stage Pipeline

SL-172154 (SIRP α -Fc-CD40L)

- **Presented Complete Dose-Escalation Data from Phase 1A Monotherapy Clinical Trial of SL-172154 in PROC at the 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. SL-172154 had near-full CD47 and CD40 target engagement and CD40-dependent pharmacodynamic effects observed at the 3 mg/kg dose. SL-172154 had a favorable safety and tolerability profile across doses. The best response per RECIST 1.1 was stable disease in six (22%) patients.
- **Completed Enrollment in Dose-escalation Portion of Phase 1A/B Clinical Trial of SL-172154 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 with azacitidine. In the dose-escalation portion of this trial, enrollment is complete. We are now enrolling patients in the dose expansion cohorts, evaluating SL-172154 in combination with azacitidine in both frontline HR-MDS patients and in frontline TP53 mutant AML. We expect to complete enrollment for the two expansion cohorts in the fourth quarter of 2023. We expect to share complete data from the dose-escalation portion of the trial and initial data from the frontline expansion cohorts in the fourth quarter 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 completed enrollment in the safety run in portion of this trial in the second quarter of 2023 and expect to complete enrollment in the expansion cohort and present initial data from the trial in the fourth quarter of 2023.
- **Enrollment Progressing 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 α), 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 α 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 α -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 α . We intend to enroll patients with broader FR α expression, including those with “high” (greater than $\geq 75\%$), “medium” ($\geq 50\%$ to $< 75\%$), and “low” ($\geq 25\%$ to $< 50\%$) expression of FR α , as determined by the VENTANA FOLR1 (FOLR1-2.1). We expect to present initial data from the trial in the fourth quarter of 2023.

Gamma Delta T Cell Engager (GADLEN) Platform

GADLEN Preclinical Compounds

- In an initial non-human primate toxicology study, presented at the 2023 Annual Meeting of the American Association for Cancer Research, we observed dose-dependent B cell depletion following administration of a CD20-directed GADLEN. Subsequently, in the second quarter of 2023, we performed an additional toxicology study in non-human primates that was designed to expand upon the initial non-human primate study. In this second study, the depth and durability of B cell depletion were inferior to that reported in published studies with other B cell depleting agents. We are working to determine the underlying scientific cause for these differences in B cell response, and whether these are due to species differences between humans and cynomolgus macaques, or due to aspects inherent to gamma delta T cell biology. We do not currently plan to file an Investigational New Drug application for any GADLEN compounds until these data are better understood.

Second-Quarter 2023 Financial Results

- **Cash and Cash Equivalents and Investments:** As of June 30, 2023, cash and cash equivalents and investments were \$117.2 million, as compared to \$214.2 million as of June 30, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were \$18.2 million for the quarter ended June 30, 2023, as compared to \$23.0 million for the quarter ended June 30, 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 \$4.7 million for the quarter ended June 30, 2023, as compared to \$4.7 million for the quarter ended June 30, 2022.
- **Net Loss:** Net loss was \$21.3 million for the quarter ended June 30, 2023, or \$0.50 per basic and diluted share, as compared to a net loss of \$27.4 million for the quarter ended June 30, 2022, or \$0.65 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 α -Fc-CD40L) is an investigational ARC[®] fusion protein designed to simultaneously inhibit the CD47/SIRP α 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 are designed to simultaneously inhibit checkpoint molecules and activate costimulatory molecules with a single therapeutic. The company's lead SL-172154 (SIRP α -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.

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 of enrollment in our clinical trials, anticipated timing for preclinical development updates, potential safety and 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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SHATTUCK LABS, INC.

CONDENSED BALANCE SHEETS
(In thousands)

	June 30, 2023	December 31,
	(unaudited)	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 71,893	\$ 47,379
Investments	45,279	113,901
Prepaid expenses and other current assets	19,278	23,304
Total current assets	136,450	184,584
Property and equipment, net	16,015	17,671
Other assets	2,805	3,069
Total assets	\$ 155,270	\$ 205,324
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,011	\$ 7,170
Accrued expenses and other current liabilities	10,983	17,795
Total current liabilities	12,994	24,965
Non-current operating lease liabilities	3,818	4,202
Total liabilities	16,812	29,167
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	399,609	396,041
Accumulated other comprehensive loss	(74)	(877)
Accumulated deficit	(261,082)	(219,012)
Total stockholders' equity	138,458	176,157
Total liabilities and stockholders' equity	\$ 155,270	\$ 205,324

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

	Three Months Ended June		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ 200	\$ 50	\$ 257	\$ 50
Operating expenses:				
Research and development	18,205	22,963	34,872	42,150
General and administrative	4,742	4,745	9,793	9,724
Expense from operations	22,947	27,708	44,665	51,874
Loss from operations	(22,747)	(27,658)	(44,408)	(51,824)
Other income (expense)	1,401	287	2,338	(75)
Net loss	\$ (21,346)	\$ (27,371)	\$ (42,070)	\$ (51,899)
Unrealized gain (loss) on investments	265	(581)	803	(548)
Comprehensive loss	\$ (21,081)	\$ (27,952)	\$ (41,267)	\$ (52,447)
Net loss per share – basic and diluted	\$ (0.50)	\$ (0.65)	\$ (0.99)	\$ (1.22)
Weighted-average shares outstanding –				

basic and diluted	42,467,664	42,380,454	42,453,513	42,369,102
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Source: Shattuck Labs, Inc.