NEWS RELEASE

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

2023-11-09

*– Positive interim data from Phase 1B clinical trial of SL-172154 in combination with pegylated liposomal doxorubicin (PLD) in platinum-resistant ovarian cancer (PROC) demonstrated an acceptable safety profile and encouraging anti-tumor activity that compares favorably to PLD as a monotherapy; expect to complete enrollment in this expansion cohort in the fourth quarter of 2023 –*

*– Topline data from Phase 1A/B clinical trial of SL-172154 in relapsed/refractory (R/R) acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (HR-MDS) patients as monotherapy and in combination with Azacitidine (AZA) to be presented in a poster presentation at the American Society of Hematology (ASH) Annual Meeting; demonstrated monotherapy response and anti-leukemic activity with an acceptable safety/tolerability profile –*

*– Completed enrollment in frontline expansion cohort in TP53 mutant AML in the third quarter and expect to complete planned enrollment in the frontline HR-MDS cohort in the fourth quarter of 2023; interim data from both cohorts expected in the fourth quarter of 2023 –*

*– Conference call and webcast to be held today, November 9th at 8:00 a.m. ET –*

AUSTIN, TX and DURHAM, NC, Nov. 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 September 30, 2023, and provided recent business highlights.

“We are encouraged by the interim data for SL-172154 in combination with PLD in a group of PROC patients with advanced disease. These data are early, and require both additional patients and longer follow-up, but provide reason for optimism in this study because an overall response rate of 25-30% with SL-171514 in combination with PLD is distinct from a benchmark response rate of 4% with PLD alone,” said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. “We look forward to sharing data from our ongoing combination clinical trial with AZA in frontline HR-MDS and TP53 mutant AML in December.”

**SL-172154 Clinical Update: *Phase 1B Clinical Trial of SL-172154 in Combination with PLD in PROC***

**Key Takeaways:** Observed three partial responses (one confirmed with 58% reduction in the sum of target lesion diameters and two unconfirmed with 100% and 31% reductions in the sum of the target lesion diameters) out of 11 evaluable patients with PROC for SL-172154 in combination with PLD. The initial data suggest SL-172154 had an acceptable safety profile in combination with PLD.

- **Data overview**: As of the data cut-off date of October 31, 2023, 16 adult patients with PROC have been dosed in the ongoing Phase 1B clinical study, of which 11 patients were evaluable for response. Patients had a median of 1.5 prior lines of systemic therapy, 47% had bulky disease measuring >5 cm, 56% were pre-treated with bevacizumab and 88% were resistant to frontline platinum regimen.
- **Preliminary anti-tumor activity:** As of the data cut-off date of October 31, 2023, three partial responses (one confirmed, two unconfirmed) had been observed for SL-172154 in combination with PLD. As of November 9, 2023, both patients with unconfirmed partial responses remain on study and have not reached the date of confirmatory response assessment.
- **Response rate benchmark for PLD:** The patient population treated in this study to date is similar to the population enrolled in the Pfizer-sponsored JAVELIN Ovarian 200 clinical trial, wherein PLD monotherapy provided an overall response rate of 4%.
- **SL-172154 plus PLD had an acceptable safety profile and is consistent with the safety profile of the individual agents:**
    - As of the data cut-off date of October 31, 2023, among the 16 treated patients, the most common SL-172154-related adverse events were infusion related reaction, nausea, fatigue, headache and neutropenia, mostly in Grade 1-2. SL-172154-related adverse events in Grade 3 or 4 were observed in 6 patients: anemia (n=2), aspartate aminotransferase increased (n=2), neutropenia (n=2), alanine aminotransferase increased (n=1), embolism (n=1) and thrombocytopenia (n=1). SL-172154-related IRRs occurred in four patients but were manageable and did not prevent the completion of dosing or lead to discontinuation. There were no Grade 5 adverse events.
    - The Phase 1B combination trial in PROC of SL-172154 in combination with PLD is using the 3 mg/kg dose of SL-172154.
- **Next steps and anticipated milestones:**
    - Completion of planned enrollment of the Phase 1B dose-expansion cohort of SL-172154 in combination with PLD in PROC expected in the fourth quarter of 2023.

**Upcoming Milestones**

***SL-172154 (SIRPα-Fc-CD40L)***

- Topline data from Phase 1A/B dose escalation clinical trial of SL-172154 in R/R AML and HR-MDS to be presented at the 65$^{th}$ ASH Annual Meeting.
- Initial data from the frontline TP53 mutant AML dose-expansion cohort and frontline HR-MDS dose-expansion cohort combining SL-172154 with AZA 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 mid-year 2024.
- Additional data from the ongoing Phase 1B clinical trial of SL-172154 in combination with PLD in PROC expected mid-year 2024.

**Third Quarter 2023 Recent Business Highlights and Other Recent Developments**

***ARC Clinical-Stage Pipeline***

SL-172154 (SIRPα-Fc-CD40L)

- **Enrollment completed in the TP53 mutant AML dose expansion cohort of the Phase 1A/B Clinical Trial of SL-172154 in combination with AZA; enrollment in the HR-MDS cohort expected to complete in the fourth quarter**: This trial is evaluating SL-172154 in combination with AZA in both frontline HR-MDS patients and frontline TP53 mutant AML patients. The data from the dose-escalation portion of the clinical trial in primarily R/R patients, which preceded the expansion cohorts in frontline patients, will be presented at the 65$^{th}$ ASH Annual Meeting. The abstract was made available on November 2, 2023. As of the May 25, 2023 data cut-off date used for the ASH abstract, 37 patients with R/R AML or HR-MDS had received SL-172154 as monotherapy or in combination with AZA in the parallel staggered dose-escalation portion of the clinical trial. Patients had a median of two prior lines of therapy. As of the data cut-off date of July 10, 2023 used for efficacy evaluation for the ASH abstract, a monotherapy response in a R/R AML patient and early signals of anti-leukemic activity (in the form of blast count reductions) in patients with R/R AML who received SL-172154 in combination with AZA were observed in a dose-dependent manner. Early signals of activity with SL-172154 in combination with AZA in frontline patients with TP53 mutant HR-MDS were also observed. Out of four evaluable previously untreated TP53 mutant HR-MDS patients, there was one complete response, one marrow complete response, and two stable disease. SL-172154 had an acceptable safety profile as monotherapy and in combination with AZA. Shattuck remains on track to share initial data in the fourth quarter of 2023 from the frontline expansion cohorts in TP53 mutant AML and HR-MDS.
- **Continued Dosing of 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 (FRα), 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 FRα positive, defined as ≥75%, as determined by the VENTANA FOLR1 (FOLR1-2.1) 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 FRα-expressing ovarian cancer cells, and that SL-172154 may broaden the activity of mirvetuximab soravtansine, particularly in patients with tumors that express lower levels of FRα. Shattuck intends to enroll patients with broader FRα expression, including those with “high” (greater than ≥75%), “medium” (≥50% to <75%), and “low” (≥25% to <50%) expression of FRα, as determined by the VENTANA FOLR1 Assay. Shattuck expects to present initial data from the trial midyear 2024.

**Upcoming Events**

- Shattuck plans to attend the following investor conference. Details will be announced prior to the event.
    - Evercore ISI HealthCONx Conference (Miami, FL), November 28-30, 2023
- 65$^{th}$ American Society of Hematology (ASH) Annual Meeting & Exposition, December 9-12, 2023
    - Poster presentation on topline data from the dose escalation portion of Phase 1A/B clinical trial of SL-172154 as monotherapy and in combination with AZA in primarily R/R AML and HR-MDS patients. The full abstract (#4278) is accessible on the ASH Congress portal and

additional details are provided here.

- Shattuck plans to hold a company-sponsored event following ASH to discuss complete data from the dose-escalation portion of the Phase 1A/B clinical trial of SL-172154 in R/R patients and initial data from the frontline expansion cohorts in HR-MDS and TP53 mutant AML. Details will be announced prior to the event.

**Conference Call**

Shattuck Labs will host a conference call at 8:00 a.m. ET today to review third quarter 2023 financial results and provide a general business overview. Investors may participate in the live call via telephone via the toll-free dial-in (888) 440-4368 and using the conference ID: 5023003. To listen to the live webcast, please visit the Investor Relations page of the Shattuck Labs website here. Participants may register for the call here. While not required, interested participants are encouraged to join 10 minutes prior to the start of the event.

A replay of the webcast will be available following the conclusion of the live call and will be accessible on the Company's website.

**Third-Quarter 2023 Financial Results**

- **Cash and Cash Equivalents and Investments:** As of September 30, 2023, cash and cash equivalents and investments were $101.1 million, as compared to $185.1 million as of September 30, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were $24.2 million for the quarter ended September 30, 2023, as compared to $18.9 million for the quarter ended September 30, 2022. This increase was primarily driven by an increase in expense associated with an increase in clinical trial costs due to increased clinical trial activity and the manufacture of clinical trial materials to support the ongoing clinical trials of SL-172154, as well as development costs for potential pipeline candidates.
- **General and Administrative (G&A) Expenses:** G&A expenses were $5.1 million for the quarter ended September 30, 2023, as compared to $6.6 million for the quarter ended September 30, 2022. This decrease was primarily driven by the recognition of a litigation settlement agreement in the third quarter of 2022.
- **Net Loss:** Net loss was $27.5 million for the quarter ended September 30, 2023, or $0.65 per basic and diluted share, as compared to a net loss of $24.6 million for the quarter ended September 30, 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 (SIRPα-Fc-CD40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the CD47/SIRPα 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 (SIRPα-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, the anticipated timing of enrollment in our clinical trials, anticipated timing for preclinical development updates, 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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**SHATTUCK LABS, INC.**
**CONDENSED BALANCE SHEETS**

**(In thousands)**

| | September 30, 2023 (unaudited) | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 40,632 | $ 47,379 |
| Investments | 60,442 | 113,901 |
| Prepaid expenses and other current assets | 11,914 | 23,304 |
| Total current assets | 112,988 | 184,584 |
| Property and equipment, net | 14,796 | 17,671 |
| Other assets | 2,673 | 3,069 |
| Total assets | $ 130,457 | $ 205,324 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,016 | $ 7,170 |
| Accrued expenses and other current liabilities | 12,043 | 17,795 |
| Total current liabilities | 14,059 | 24,965 |
| Non-current operating lease liabilities | 3,615 | 4,202 |
| Total liabilities | 17,674 | 29,167 |
| Stockholders' equity: | | |
| Common stock | 5 | 5 |
| Additional paid-in capital | 401,394 | 396,041 |
| Accumulated other comprehensive loss | 7 | (877) |
| Accumulated deficit | (288,623) | (219,012) |
| Total stockholders' equity | 112,783 | 176,157 |
| Total liabilities and stockholders' equity | $ 130,457 | $ 205,324 |

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

**(In thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Collaboration revenue | $ 686 | $ 212 | $ 943 | $ 262 |
| Operating expenses: | | | | |
| Research and development | 24,211 | 18,862 | 59,083 | 61,012 |
| General and administrative | 5,073 | 6,579 | 14,866 | 16,303 |
| Expense from operations | 29,284 | 25,441 | 73,949 | 77,315 |
| Loss from operations | (28,598) | (25,229) | (73,006) | (77,053) |
| Other income | 1,057 | 594 | 3,395 | 519 |
| Net loss | $ (27,541) | $ (24,635) | $ (69,611) | $ (76,534) |
| Unrealized gain (loss) on investments | 81 | (226) | 884 | (774) |

| | | | | |
|---|---|---|---|---|
| Comprehensive loss | $ (27,460) | $ (24,861) | $ (68,727) | $ (77,308) |
| Net loss per share – basic and diluted | $ (0.65) | $ (0.58) | $ (1.64) | $ (1.81) |
| Weighted-average shares outstanding – basic and diluted | 42,477,642 | 42,386,470 | 42,461,644 | 42,374,955 |

Source: Shattuck Labs, Inc.