NEWS RELEASE

# Shattuck Labs Reports Fourth-Quarter and Full-Year 2022 Financial Results and Provides Business Updates

2023-02-23

*– Initiated enrollment in Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in platinum-resistant ovarian cancer –*

*– Dosed patients in first combination cohort with azacitidine in ongoing Phase 1A/B clinical trial of SL-172154 in acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (HR-MDS) –*

*– Announced two potential lead product candidates, currently in preclinical development, from the Gamma Delta T Cell Engager (GADLEN) platform –*

*– Appointed Dr. George Fromm and Dr. Suresh de Silva as Chief Scientific Officers (CSO) of the ARC and GADLEN platforms, respectively –*

*– Completed Phase 1 dose-escalation trial of SL-279252 and announces discontinuation of the SL-279252 program –*

AUSTIN, TX and DURHAM, NC, Feb. 23, 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 fourth quarter and full year ended December 31, 2022 and provided recent business highlights.

“During the fourth quarter of 2022, we continued to focus on clinical execution to position ourselves for key clinical data readouts for SL-172154 in 2023. Enrollment in our AML/HR-MDS clinical trial of SL-172154 is moving along nicely, and, in the fourth quarter, we advanced into the first combination cohort with azacitidine. This keeps us on track to share initial data from the dose-escalation portion of this trial from relapsed/refractory AML/HR-MDS patients both as monotherapy and in combination with azacitidine in the first half of 2023. As it relates to our trials in platinum-resistant ovarian cancer, in early 2022 we established a collaboration with ImmunoGen to combine SL-172154 with

mirvetuximab soravtansine and, in the fourth quarter, we initiated enrollment in this Phase 1B clinical trial. We expect initial data from the combination trial with SL-172154 and liposomal doxorubicin midyear 2023, and we expect initial data from the combination trial of SL-172154 and mirvetuximab soravtansine in the second half of 2023," said Taylor Schreiber, M.D., Ph.D., and Chief Executive Officer of Shattuck. "I am also very pleased to announce the promotion of Dr. George Fromm to CSO of the ARC platform and Dr. Suresh de Silva to CSO of the GADLEN platform. We look forward to benefiting from the expertise of these scientific program leaders as we continue our momentum in 2023. Drs. Fromm and de Silva have been invaluable to Shattuck from the time they each joined the company in 2017, and they will continue to play a critical role as we build-out our pipeline over the coming years. 2023 is an important year for Shattuck, with multiple data readouts, which we believe will establish SL-172154 as both a differentiated CD47 inhibitor and a CD40 agonist capable of activating the CD40 pathway in human cancer patients. We expect that these data will position Shattuck well for continued growth in the years ahead."

"After enrolling patients in the final dose levels of 12 and 24 mg/kg with the SL-279252 clinical program, and not meeting a stringent efficacy threshold required to justify further development, we have decided to discontinue development of SL-279252. The development program for SL-279252 has yielded tremendously important preclinical, translational, and clinical data for the ARC platform, and we thank the patients and their families for participating in our clinical trial. We remain focused on delivering novel therapeutics that benefit patients with cancer with high unmet need and look forward to the combination data in both of our ongoing clinical trials with SL-172154 in the coming quarters," continued Dr. Schreiber.

**Clinical Milestones Expected in 2023**

**ARC Platform**

SL-172154 (SIRPα-Fc-CD40L)

- Complete data from Phase 1A dose-escalation clinical trial of SL-172154 as monotherapy in platinum-resistant ovarian cancer expected midyear 2023
- Initial data from Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in platinum-resistant ovarian cancer expected midyear 2023
- Initial dose-escalation data, as monotherapy and in combination with azacitidine, for Phase 1A/B clinical trial of SL-172154 in relapsed/refractory AML and HR-MDS expected in the first half of 2023
- Complete dose-escalation data, as monotherapy and in combination with azacitidine, for Phase 1A/B clinical trial of SL-172154 in AML and HR-MDS and initial dose-expansion cohort data with SL-172154 in combination with azacitidine in frontline TP53 mutant AML and HR-MDS expected in the second half of 2023
- Initial data from Phase 1B clinical trial of SL-172154 in combination with mirvetuximab soravtansine in platinum-resistant ovarian cancer expected in the second half of 2023

**GADLEN Platform**

GADLEN Preclinical Compounds

- Additional detail and further program guidance regarding the advancement of potential product candidates from the GADLEN platform expected in 2023

**Fourth Quarter 2022 Recent Business Highlights and Other Recent Developments**

***ARC Clinical-Stage Pipeline***

**SL-172154 (SIRPα-Fc-CD40L)**

- **Completed Phase 1A Monotherapy Dose-Escalation Clinical Trial of SL-172154 in Platinum-Resistant Ovarian Cancer:** 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 advanced platinum-resistant ovarian cancer. We reached a maximum administered dose of 10.0 mg/kg and expect to present complete dose-escalation data from the trial midyear 2023.
- **Dosed First Patients in First Combination Cohort with Azacitidine in Ongoing Phase 1A/B Clinical Trial 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. In AML, SL-172154 may be evaluated in combination with azacitidine and venetoclax. In both HR-MDS and TP53 mutant AML, SL-172154 may be evaluated in combination with azacitidine. Patients have been dosed in both the monotherapy and combination dose-escalation cohorts of this trial and enrollment is ongoing. Dose escalation will continue in a parallel staggered manner, and initial dose-escalation data, as monotherapy and in combination with azacitidine, are expected in the first half of 2023.
- **Enrollment Progressing in Phase 1B Clinical Trial of SL-172154 in Combination with Liposomal Doxorubicin in Advanced Platinum-Resistant Ovarian Cancer:** 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 3.0 mg/kg, in combination with liposomal doxorubicin in patients with advanced platinum-resistant ovarian cancer. We expect to present initial data from this trial in combination with liposomal doxorubicin midyear 2023.
- **Initiated Enrollment in Phase 1B Clinical Trial of SL-172154 in Combination with Mirvetuximab Soravtansine in Advanced Platinum-Resistant Ovarian Cancer.** This trial is evaluating the safety, pharmacokinetics, pharmacodynamic effects, and preliminary anti-tumor activity of SL-172154 administered in combination with mirvetuximab soravtansine in subjects with platinum-resistant ovarian, primary peritoneal, or fallopian tube cancers. Mirvetuximab soravtansine is an antibody-drug conjugate targeting folate receptor alpha, or 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 platinum-resistant ovarian cancer patients whose tumors are shown to be FRα positive, defined as ≥75%, as determined by the VENTANA FOLR1 (FOLR1-2.1) Assay, using the PS2+ scoring method. Pre-clinical 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. We intend to enroll patients with broader FRα expression, including those with “high” (greater than ≥75% of tumor cells staining with 2+ intensity), “medium” (≥50% to <75% of tumor cells staining with 2+ intensity) , and “low” (≥25% to <50% of tumor cells staining with 2+ intensity) expression of FRα, as determined by the VENTANA FOLR1 (FOLR1-2.1) Assay, using the PS2+ scoring method. We expect to present initial data from this trial in combination with mirvetuximab soravtansine in the second half of 2023.

**SL-279252 (PD1-Fc-OX40L)**

- **Completed Phase 1 Dose Escalation Clinical Trial of SL-279252 in Advanced Solid Tumors**

**and Announces Discontinuation of Clinical Development of the SL-279252 Program:** In the fourth quarter of 2021, we reported initial data from this trial demonstrating evidence of initial anti-tumor activity and dose-dependent pharmacodynamic activity. As previously stated, our internal benchmark for continued program development of SL-279252 was response rates equal or exceeding 20% in the 12 and 24 mg/kg cohorts. We did not observe an overall response rate necessary to justify continued development in a very difficult PD-1 relapsed/refractory patient population, and we are announcing the discontinuation of clinical development of SL-279252.

***Gamma Delta T Cell Engager (GADLEN) Preclinical Pipeline***

**Preclinical Pipeline Development**

- **Announced two potential product candidates, currently in preclinical development, from the GADLEN platform—one targeting the CD20 antigen intended for development in autoimmune disease, and a second targeting the B7-H3 antigen for development in oncology:** As Shattuck advances its preclinical pipeline, we anticipate further program guidance regarding the advancement of potential product candidates from the GADLEN platform in 2023.

**Corporate Update**

- **Appointed CSOs for ARC and GADLEN Platforms:** In January 2023, Dr. George Fromm was promoted to CSO of the ARC platform, and Dr. Suresh de Silva was promoted to CSO of the GADLEN platform. Dr. Fromm joined Shattuck Labs in 2017 and is one of its scientific co-founders. He previously served as Shattuck's Vice President of R&D and co-led the preclinical development of SL-279252 and SL-172154 into clinical trials. Earlier, Dr. Fromm served as the Senior Director of Research and Development at Heat Biologics, Inc., where he directed the discovery and clinical-based research efforts for their phase I/II trials and co-invented a "next-generation" vaccine platform that combines a cell-based immunotherapy vaccine and a T cell costimulatory fusion protein in a single treatment. Dr. de Silva previously served as Shattuck's Vice President of Product Development from 2018-2022 and as Shattuck's Executive Director of Research and Development from 2017 to 2018. Dr. de Silva joined Shattuck in 2017 and is one of its scientific co-founders and co-led the preclinical development of SL-279252 and SL-172154. Prior to joining Shattuck, Dr. de Silva served as the Director of Research and Development at Heat Biologics, Inc. in Durham, NC, where he led external research collaborations and co-developed the ComPact cell-based vaccine platform.

**Upcoming Events**

- **American Association for Cancer Research Annual Meeting (AACR), April 14-19, 2023**
  - Poster presentation on the preclinical development of GADLEN compounds
- **Shattuck plans to attend the following investor conferences. Details of the presentations and webcasts will be announced prior to the events.**
  - Cowen 43rd Annual Healthcare Conference, March 6-8, 2023
  - Oppenheimer 33rd Annual Healthcare Conference, March 13-15, 2023
  - Needham 22nd Annual Healthcare Conference, April 17-20, 2023

**Fourth-Quarter and Full-Year 2022 Financial Results**

- **Cash Position:** As of December 31, 2022, cash and cash equivalents and investments were $161.3 million, as compared to $268.8 million as of December 31, 2021.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended December

31, 2022 were $21.9 million, as compared to $16.2 million for the quarter ended December 31, 2021. R&D expenses for the year ended December 31, 2022 were $82.9 million, as compared to $56.6 million for the year ended December 31, 2021. This increase was primarily driven by increases in manufacturing of trial materials to support clinical development of our ongoing clinical trials, personnel-related costs, and lab supplies.

- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended December 31, 2022 were $4.8 million, as compared to $4.6 million for the quarter ended December 31, 2021. General and administrative expenses for the year ended December 31, 2022 were $21.1 million, as compared to $18.7 million for the year ended December 31, 2021. This increase was primarily driven by a litigation settlement of $1.4 million and increases in personnel-related and other operating costs.
- **Net Loss:** Net loss was $25.4 million for the quarter ended December 31, 2022, or $0.60 per basic and diluted share, as compared to a net income of $7.8 million for the quarter ended December 31, 2021, or $0.19 per basic share and $0.18 per diluted share. Net loss for the year ended December 31, 2022 was $101.9 million, or $2.41 per basic and diluted share, as compared to $45.0 million, or $1.07 per basic and diluted share, for the year ended December 31, 2021.

**2023 Financial Guidance**

Shattuck believes its cash and cash equivalents and investments will be sufficient to fund its operations into the second half of 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 advanced platinum-resistant ovarian cancer (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 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. Additionally, the company is advancing a proprietary Gamma Delta T Cell Engager, GADLEN™, platform, which is designed to bridge gamma delta T cells to tumor antigens for the treatment of patients with cancer. 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 for preclinical development updates, potential 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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## FINANCIAL INFORMATION

### SHATTUCK LABS, INC.
### BALANCE SHEETS

**(In thousands)**

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 47,379 | $ 92,268 |
| Investments | 113,901 | 176,536 |
| Prepaid expenses and other current assets | 23,304 | 19,462 |
| Total current assets | 184,584 | 288,266 |
| Property and equipment, net | 17,671 | 9,938 |
| Other assets | 3,069 | 381 |
| Total assets | $ 205,324 | $ 298,585 |

| | | |
|---|---|---|
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,170 | $ 10,012 |
| Accrued expenses and other current liabilities | 17,795 | 14,574 |
| Total current liabilities | 24,965 | 24,586 |
| Non-current operating lease liabilities | 4,202 | — |
| Deferred rent | — | 2,213 |
| Total liabilities | 29,167 | 26,799 |
| Stockholders' equity: | | |
| Common stock | 5 | 5 |
| Additional paid-in capital | 396,041 | 389,408 |
| Accumulated other comprehensive loss | (877) | (560) |
| Accumulated deficit | (219,012) | (117,067) |
| Total stockholders' equity | 176,157 | 271,786 |
| Total liabilities and stockholders' equity | $ 205,324 | $ 298,585 |

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

| | Three Months Ended December 31, (Unaudited) | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Collaboration revenue | $ 390 | $ 30,078 | $ 652 | $ 30,017 |
| Operating expenses: | | | | |
| Research and development | 21,887 | 16,207 | 82,899 | 56,563 |
| General and administrative | 4,779 | 4,624 | 21,082 | 18,723 |
| Expense from operations | 26,666 | 20,831 | 103,981 | 75,286 |
| Gain (loss) from operations | (26,276) | 9,247 | (103,329) | (45,269) |
| Other income (expense): | | | | |
| Interest income (expense) | 908 | (1,321) | 1,592 | 625 |
| Other | (43) | (79) | (208) | (330) |
| Total other income (expense) | 865 | (1,400) | 1,384 | 295 |
| Net income (loss) | $ (25,411) | $ 7,847 | $ (101,945) | $ (44,974) |
| Unrealized gain (loss) on investments | 457 | 1,267 | (317) | (497) |
| Comprehensive gain (loss) | $ (24,954) | $ 9,114 | $ (102,262) | $ (45,471) |
| Basic and Diluted Per Common Share Data: | | | | |
| Net earnings (loss) per share - basic | $ (0.60) | $ 0.19 | $ (2.41) | $ (1.07) |
| Weighted-average shares outstanding - basic | 42,390,586 | 42,286,190 | 42,378,895 | 42,032,384 |
| Net earnings (loss) per share - diluted | $ (0.60) | $ 0.18 | $ (2.41) | $ (1.07) |
| Weighted-average shares outstanding - diluted | 42,390,586 | 44,734,866 | 42,378,895 | 42,032,384 |

Source: Shattuck Labs, Inc.