NEWS RELEASE

Shattuck Labs Announces Orphan Drug Designation Granted by the U.S. Food and Drug Administration (FDA) for SL-172154 for the Treatment of Acute Myeloid Leukemia (AML)

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AUSTIN, TX and DURHAM, NC, June 10, 2024 (GLOBE NEWSWIRE) -- Shattuck Labs, Inc. (Shattuck) (Nasdaq: STTK), a clinical-stage biotechnology company pioneering the development of bifunctional fusion proteins as a new class of biologic medicine for the treatment of patients with cancer and autoimmune disease, today announced that the U.S. FDA has granted orphan drug designation (ODD) to lead clinical candidate SL-172154 for the treatment of AML.

“AML patients have few options for treatment and a poor prognosis. FDA’s decision to grant orphan drug designation to SL-172154 highlights the urgent need for new treatment options,” said Taylor Schreiber, M.D., Ph.D., Chief Executive Officer of Shattuck. “This is an important first step in our progression to later-stage clinical studies, and we look forward to presenting additional data from the Phase 1B dose expansion clinical trial of SL-172154 with azacitidine in frontline higher-risk myelodysplastic syndromes and TP53m AML patients during a poster presentation at the European Hematology Association 2024 Congress.”

The FDA’s Office of Orphan Products Development grants orphan status to drugs being developed to treat, diagnose, or prevent a rare disease or condition affecting fewer than 200,000 people in the United States. Orphan Drug Designation is designed to provide drug developers with various benefits to support the development of novel drugs, including the potential for market exclusivity for seven years upon FDA approval, eligibility for tax credits for qualified clinical trials, and waiver of application fees.

About AML
AML is a hematologic malignancy that develops from clonal expansion of myeloid precursors residing in the bone marrow. In patients with AML, leukemic blasts infiltrate the bone marrow and disrupt normal hematopoiesis. According to the National Cancer Institutes’ Surveillance, Epidemiology, and End Results Program, in 2023, there were approximately 20,380 new cases of AML in the U.S., with 11,310 deaths attributed to the disease. The median age of diagnosis is 68 years with approximately

one-third of patients being diagnosed over the age of 75. More than 70% of patients 65 years or older will die from their disease within one year of diagnosis. As of 2019, the five-year relative survival rate for acute myeloid leukemia was approximately 32%.

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 platinum-resistant ovarian cancer (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, statements regarding: future presentations of clinical data; clinical development plans and strategies for SL-172154; timing of anticipated clinical data; future plans for Shattuck's pipeline; and Shattuck's strategies. Words such as "anticipate," "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 the company believes 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 the company 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 Shattuck's filings with the U.S. Securities and Exchange Commission (SEC)), many of which are beyond the company's control and subject to change. Actual results could be materially different. Risks and uncertainties which could cause such outcomes to change include: global macroeconomic conditions and related volatility; expectations regarding the initiation, progress, and expected results of Shattuck's preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of the company's 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 Shattuck's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent disclosure documents filed with the SEC. Shattuck claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. Shattuck expressly disclaims 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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