Salarius Pharmaceuticals Announces New Clinical Trial to Study Seclidemstat in Hematologic Cancers

Clinical trial to target patients with Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML), both cancers that can progress into Acute Myeloid Leukemia (AML)

HOUSTON, June 15, 2021 (GLOBE NEWSWIRE) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company developing potential new medicines for patients with pediatric cancers, solid tumors, and other cancers, today announced the initiation of a clinical trial to investigate seclidemstat, a novel lysine specific demethylase 1 (LSD1) inhibitor, as a potential treatment for hematologic cancers. This investigator-initiated Phase 1/2 trial will be led by Dr. Guillermo Montalban-Bravo from the Department of Leukemia at The University of Texas MD Anderson Cancer Center.

The trial will be an open label, dose-finding, dose-expansion study to determine the maximum tolerated dose (MTD) and the safety and tolerability of seclidemstat when used in combination with azacytidine as a treatment for Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML). MDS and CMML are blood cancers that can progress into a deadly form of leukemia, Acute Myeloid Leukemia (AML). The trial was initiated because of compelling preclinical data in which seclidemstat demonstrated anti-proliferative activity across hematologic cancers and synergy when used in combination with azacytidine.

Seclidemstat is a differentiated, oral, reversible inhibitor of LSD1, a key enzyme implicated in several cancer types. Seclidemstat is being studied in various solid tumor trials that have indicated seclidemstat has a manageable safety profile with preliminary evidence of anti-tumor activity.

"We look forward to exploring the potential of seclidemstat in Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia," said Nadeem Mirza, M.D., M.P.H., Senior Vice President Clinical Development at Salarius Pharmaceuticals. "These are hard to treat blood cancers, and if patients progress to Acute Myeloid Leukemia, they face a bleak prognosis. New treatment options are desperately needed, and this study provides hope to patients battling these devastating cancers."

The dose-escalation stage of the Phase 1/2 trial will enroll patients aged 18 and older with MDS or CMML. Patients will receive 75 mg/m^2 of azacytidine, administered intravenously (IV) or subcutaneously (SC), on days one through seven of each 28-day cycle in combination with an escalating, twice-daily dose of seclidemstat administered as an oral tablet. Once MTD of the combination is determined by the Safety Review Committee, the study enters a dose-expansion stage that will enroll additional patients to confirm the safety and tolerability profile for seclidemstat in combination with azacytidine and capture efficacy data regarding overall response rate, duration of response, leukemia-free survival, relapse-free survival, and overall survival.

"We are very excited about this collaboration to research seclidemstat as a potential new treatment for Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia, two aggressive and potentially deadly blood cancers," stated David Arthur, CEO of Salarius Pharmaceuticals. "This clinical trial represents

an additional step in developing seclidemstat for use in hematologic and other cancers and is based on preclinical and clinical research suggesting that LSD1 inhibition has an effect on hematologic cancers. We are optimistic that seclidemstat could hold a key to treating these and other devastating cancers where LSD1 inhibition plays a role in the development and progression of cancer."

Funding for the trial will be provided by MD Anderson and Salarius, with Salarius also providing seclidemstat to investigators for the clinical trial. More information on the clinical trial is available at www.clinicaltrials.gov.

About Salarius Pharmaceuticals

Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing cancer therapies for patients in need of new treatment options. Salarius' lead candidate, seclidemstat, is being studied as a potential treatment for pediatric cancers, solid tumors and other cancers with limited treatment options. Seclidemstat is currently in a Phase 1/2 clinical trial for relapsed/refractory Ewing sarcoma and FET-translocated sarcomas. Seclidemstat has received Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation in Ewing sarcoma from the U.S. Food and Drug Administration. Salarius is also developing seclidemstat for several cancers with high unmet medical need, with a second Phase 1/2 clinical study in advanced solid tumors, including prostate, breast, and ovarian cancers. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and was also a recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit salariuspharma.com or follow Salarius on Twitter and LinkedIn.

Forward-Looking Statements

This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve substantial risks and uncertainties and include statements: about the scope of the expected collaboration; about the findings of any study conducted through the collaboration including any findings regarding the safety and tolerability of seclidemstat in combination with azacytidine in the treatment of Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML); that discuss the role of seclidemstat in any studies conducted through the collaboration; related to how findings in any study involving seclidemstat may conform to any findings from previous preclinical and clinical trials; preclinical and clinical research results and the ability and potential for LSD1 inhibition to address hematological cancers; and related to the ability to determine the MTD of the combination or entering a dose-expansion stage. All statements, other than statements of historical facts, included in this press release regarding the Company's plans and objectives, expectations and assumptions of management are forward-looking statements. The use of certain words, including the words "estimate," "project," "intend," "expect," "believe," "anticipate," "will," "plan," "could," "may" and similar expressions are intended to identify forward-looking statements. The Company may not actually achieve the plans, intentions or expectations disclosed in the forward-looking statements and you should not place undue reliance on the Company's

forward-looking statements. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements including receipt of regulatory approvals and market conditions. The forward-looking statements are made as of this date and the Company does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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