

Salarius Pharmaceuticals Receives FDA Fast Track Designation for Lead Drug Candidate, Seclidemstat, in Relapsed or Refractory Ewing Sarcoma

Phase 1/2 Clinical Study Now Underway; Salarius Targeting Key Safety and Efficacy Data Milestones in 2020

HOUSTON, Dec. 16, 2019 (GLOBE NEWSWIRE) -- Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biotechnology company targeting cancers caused by mis-regulated gene expression, announced today that its lead investigational drug candidate, Seclidemstat, has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with Ewing sarcoma who have relapsed or are refractory to standard-of-care therapy. Seclidemstat, a potent reversible LSD1 inhibitor, is the subject of an ongoing Phase 1/2 clinical study in Ewing sarcoma.

David Arthur, President and Chief Executive Officer of Salarius, stated, "Securing FDA Fast Track Designation for Seclidemstat in Ewing sarcoma is an achievement for Salarius in the ongoing development of the drug and recognition that there is an unmet need to bring much needed hope to patients and their families suffering through this devastating disease. Coupled with Seclidemstat's previously granted Orphan Drug Designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration, we feel well positioned to take advantage of the FDA's expedited programs for drug development and review."

"Ewing sarcoma is a rare and deadly bone cancer that most often strikes children and young adults and for which there are no targeted therapies approved. Seclidemstat has demonstrated a potential to address this considerable unmet need, and we look forward to rapidly advancing its development so that it soon may be available to those patients most in need," stated Damon Reed, M.D., Director of the Adolescent and Young Adult

Program at the Moffitt Cancer Center and Principle Investigator of the Salarius Ewing sarcoma clinical trial.

Fast Track is a process designed by the FDA to expedite the development and review of new drugs with the potential to treat serious or life-threatening conditions and fill unmet medical needs. The aim is to streamline regulatory submissions and enable more frequent communications with the agency to assure that questions and issues are resolved quickly, which often leads to earlier drug approval and access by patients.

About Seclidemstat

Seclidemstat is a first-in-class, oral, small molecule designed for the reversible and noncompetitive inhibition of the LSD1 enzyme. Seclidemstat is based on the research of Dr. Sunil Sharma, Salarius' co-founder, into LSD1 inhibition during his tenure at the University of Utah's Huntsman Cancer Institute. As a reversible inhibitor, Seclidemstat could offer more efficacy, more flexible dosing and less toxicity. Salarius expects to release early cohort data early next year from its Ewing sarcoma study and a second Phase 1 clinical study in advanced solid tumors, including prostate, breast and ovarian cancers. A preclinical program in glioblastoma is underway at the Barrow Neurological Institute's Ivy Brain Tumor Center.

More information about Salarius' ongoing Ewing sarcoma trial is available at ClinicalTrials.gov and on the company website, salariuspharma.com. Active clinical trial sites include, Memorial Sloan Kettering Cancer Center in New York City, Nationwide Children's Hospital in Columbus, OH, Johns Hopkins All Children's Hospital in St. Petersburg, FL; Children's Hospital of Los Angeles in Los Angeles, CA; Moffitt Cancer Center in Tampa, FL; Dana-Farber Cancer Institute in Boston, MA; MD Anderson Cancer Center in Houston, TX; and the Sarcoma Oncology Center in Santa Monica, CA.

About Salarius Pharmaceuticals

Salarius Pharmaceuticals, Inc. is a clinical-stage oncology company targeting the epigenetic causes of cancers and is developing treatments for patients that need them the most. Epigenetics refers to the regulatory system that affects gene expression. In some cancers, epigenetic regulators often become dysregulated and incorrectly turn genes on or off leading to cancer progression. Drugs that can safely modify the activity of these epigenetic regulators may correct the gene changes that are driving the disease. The company's lead candidate, Seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has Orphan Drug Designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. Salarius believes that Seclidemstat is one of only two reversible inhibitors of the epigenetic modulator LSD1 currently in human trials, and that it could have potential for improved safety and efficacy compared to other LSD1-targeted therapies. Salarius is also developing Seclidemstat for several cancers with high unmet medical need, with a second Phase 1 clinical study in advanced solid tumors, including prostate, breast and ovarian cancers. Salarius receives financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and is also the recipient of an \$18.7 million Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit salariuspharma.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. These forward-looking statements may be identified by terms such as "will," "can," "could," "believe," "feel," "plan," "allow," "will," "expect," "provide," "able to," "position," "anticipate," "progress," "potential," "target," and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements regarding: the current study of Seclidemstat in a Phase 1/2 clinical trial in Ewing sarcoma; the company's targeting of key safety and efficacy data milestones in 2020; the company's belief that it is well positioned to take

advantage of the FDA's expedited programs for drug development and review; the potential of Seclidemstat, including the potential to offer more efficacy, more flexible dosing and less toxicity; the company's expectation that it may release early cohort data early next year from its Ewing sarcoma study and a second Phase 1 clinical study in advanced solid tumors; the company's belief that Seclidemstat is one of only two reversible inhibitors of the epigenetic modulator LSD1 currently in human trials, and that it could have potential for improved safety and efficacy compared to other LSD1-targeted therapies; and the company's development of Seclidemstat for several cancers with high unmet medical need, with a second Phase 1 clinical study in advanced solid tumors, including prostate, breast and ovarian cancers. Salarius may not actually achieve the plans, carry out the intentions or meet the expectations or objectives disclosed in the forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements are subject to risks and uncertainties which could cause actual results and performance to differ materially from those discussed in the forward-looking statements. These risks and uncertainties include, but are not limited to, the following: the ability of the company to raise additional capital to meet the company's business operational needs and to achieve its business objectives and strategy; the company's ability to project future capital needs and cash utilization; available sources of cash, including from CPRIT and its equity line; future clinical trial results; that the results of studies and clinical trials may not be predictive of future clinical trial results; the sufficiency of Salarius' intellectual property protection; risks related to the drug development and the regulatory approval process; the competitive landscape and other industry-related risks; market conditions which may impact the ability of Salarius access capital under its equity line; the possibility of unexpected expenses or other uses of Salarius' cash resources; and other risks described in Salarius' filings with the Securities and Exchange Commission, including those under the heading "Risk Factors." The forward-looking statements contained in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Salarius disclaims any intent or obligation to update these forward-looking

statements to reflect events or circumstances that exist after the date on which they were made.

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