Salarius Pharmaceuticals Achieves Dose-Escalation Milestones in Ongoing Phase 1/2 Ewing Sarcoma and Phase 1 Advanced Solid Tumor Clinical Trials

Fourth Level Dosing Cohorts Now Proceeding Following Safety Review Committee Clearance

HOUSTON, Sept. 24, 2019 (GLOBE NEWSWIRE) -- (Nasdaq: SLRX), a clinical-stage oncology company targeting the epigenetic causes of cancers, announced today that the Safety Review Committees overseeing the Phase 1/2 clinical study of Seclidemstat in Ewing sarcoma and the Phase 1 study of Seclidemstat in patients with advanced solid tumors (AST) have approved the advancement of each study to the fourth level dosing cohort.

The Phase 1/2 clinical trial of Seclidemstat in Ewing sarcoma and Phase 1 AST clinical trial are designed as open-label dose-finding studies to determine the maximum tolerated dose (MTD) and initial safety profile of Seclidemstat. Seclidemstat is administered daily as an oral tablet, with each cohort receiving an increased dose of study medication. This MTD, as determined by the Safety Review Committee, will then be used to treat a larger group of patients to confirm the safety profile for Seclidemstat and capture additional information regarding pharmacokinetics and potential preliminary efficacy.

David Arthur, President and Chief Executive Officer of Salarius, stated, “Clearance from the Safety Review Committees to proceed to the higher dosing cohort is an important milestone in the ongoing clinical trials. Ultimately, our goal with these studies is to pinpoint the optimal dose of Seclidemstat, which, in addition to determining the safety parameters of the drug, will enable us to obtain key pharmacokinetic information and, potentially, initial efficacy data. Based on current projections we are on track to reach maximum tolerated dose early next year and report early patient data from both studies in 2020.”

The Ewing sarcoma study opened patient enrollment in Q3 2018 and is currently enrolling patients of 12 years of age or older at leading cancer centers in the U.S., including Johns Hopkins All Children’s Hospital, Children’s Hospital of Los Angeles, Moffitt Cancer Center, Dana-Farber Cancer Institute and MD Anderson Cancer Center. Most recently, the Sarcoma Oncology Center in California was added, bringing the total number of active clinical trial sites to six. The Safety Review Committee recently cleared the third dose level (300 mg Seclidemstat twice-daily), and the fourth dose level is currently enrolling (600 mg Seclidemstat twice-daily). Based on the first 3 dose levels, the pharmacokinetic profile (i.e., how the drug is distributed in the body following administration) appears to be dose proportional.

In June 2019, the Advanced Solid Tumor study began enrolling patients with advanced or recurrent solid tumors including, but not limited to, breast, ovarian and prostate cancer. All study patients had received standard of care therapies but continued to experience progression of their disease. Similar to the Ewing sarcoma study, the Safety Review Committee has cleared the 300 mg dose twice-daily and the 600 mg twice-daily dosing group is currently enrolling patients across the two active sites, HonorHealth in Arizona and the Sarcoma Oncology Center in California.

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 are able to 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 a number of 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 .

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. Examples of such statements include, but are not limited to, statements relating to: the potential for Seclidemstat to target the epigenetic causes of cancers including prostate, breast and ovarian cancers; expected timing and results of clinical studies, including the company's expectations on reaching maximum tolerated dose early next year and reporting early patient data from both studies in 2020; the pharmacokinetic profile appearing to be dose proportional; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. 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; 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;

and the competitive landscape and other industry-related risks. 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.

Contacts

Investor Relations

Jeremy Feffer
Managing Director
(212) 915-2568

Media Relations:

Johanna Bennett
Senior Vice President
(212) 375-2686

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