Salarius Pharmaceuticals to Expand Clinical Program to Target Additional Sarcomas in Ewing Sarcoma Phase 1/2 Clinical Trial

Pre-Clinical Data and Early Clinical Observations Support Company's Decision to Research Seclidemstat as a Potential Treatment in Ewing-Related Sarcomas

HOUSTON, July, 29, 2020 (GLOBE NEWSWIRE) -- Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical stage oncology company targeting cancers caused by dysregulated gene expression, today announced the expansion of its ongoing clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma to include additional select sarcomas that share a similar biology to Ewing sarcoma, also known as Ewing-related sarcomas. The planned amendment to the ongoing clinical trial will allow patients with Ewing-related sarcomas, which share a similar gene rearrangement to Ewing sarcoma, to enroll in the ongoing trial. Sarcomas of interest include myxoid liposarcoma, desmoplastic small round cell tumors and other sarcomas with FET family translocations, i.e. Ewing-related sarcomas.

Seclidemstat's potential as a treatment for Ewing-related sarcomas is supported by pre-clinical data and early clinical data observations from the ongoing Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma. A refractory Ewing sarcoma patient treated with seclidemstat for six months demonstrated a reduction of over 80% in prospectively defined target lesions. Target lesions generally represent a patient's largest measurable tumors. However, at eight weeks, an increase in non-target lesions resulted in an overall patient classification of progressive disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST).

Salarius believes this prospectively defined and measured reduction of over 80% in target lesions by single agent seclidemstat treatment demonstrates preliminary drug activity in a patient with refractory Ewing sarcoma. Salarius also believes this demonstration of drug activity coupled with pre-clinical data supports clinical research of seclidemstat as a potential treatment for Ewing-related sarcomas and the expansion of the current clinical program.

The current Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma is an open-label dose-finding trial intended to characterize the pharmacokinetics (PK) and initial safety profile of seclidemstat, and also determine the maximum tolerated dose (MTD). Once MTD is established, the trial will enter a dose expansion phase that will enroll up to 20 Ewing sarcoma patients to expand the safety and PK profile of seclidemstat and assess preliminary efficacy data. Under the planned amendment to the trial protocol, a second cohort of the expansion phase will enroll up to 30 additional patients with either myxoid liposarcoma, desmoplastic small round cell tumors or other Ewing-related sarcomas.

"Preclinical data and early clinical observations involving seclidemstat suggest that the drug may have applicability in several sarcomas that share key characteristics of Ewing sarcoma," 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. "Based on this potential, and the pressing need

for better treatment options for sarcomas, including Ewing sarcoma, we are pleased to extend the ongoing Phase 1/2 clinical trial to additional sarcoma subtypes."

"This is an exciting opportunity to validate our growing belief that seclidemstat could have a significant impact on the treatment of Ewing sarcoma, as well the treatment of Ewing-related sarcomas. Expanding the ongoing trial to include patients with Ewing-related sarcomas offers the potential to develop seclidemstat for even broader patient populations" stated David Arthur, President and CEO of Salarius Pharmaceuticals.

Mr. Arthur added, "We continue to be pleased by the progress we are making in our Ewing sarcoma clinical program and I would like to thank the National Pediatric Cancer Foundation and the Cancer Prevention and Research Institute of Texas for their ongoing support in researching potential treatments for pediatric cancers."

Seclidemstat is an oral treatment that targets cancers driven, at least in part, by the overexpression of lysine-specific demethylase one, or LSD1, an enzyme that plays a key role in the development and growth of Ewing sarcoma and other cancers. Seclidemstat is a reversible inhibitor of the LSD1 enzyme.

A second Phase 1/2 clinical dose-escalation trial is also underway investigating seclidemstat in advanced solid tumors (AST).

About Salarius Pharmaceuticals, Inc.

Salarius Pharmaceuticals, Inc. is a clinical-stage oncology company targeting cancers caused by dysregulated gene expression, or 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. Salarius' lead candidate, seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. Salarius is also developing seclidemstat for a number of cancers, with a second Phase 1/2 clinical study in advanced solid tumors, including prostate, breast and ovarian cancers.

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," "could," "believe," "plan," "will," "expect," "target," and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements regarding the number of patients with sarcomas that share similar translocations to Ewing sarcoma that will be enrolled under the amended protocols and the types of sarcoma such patients will have; the applicability of seclidemstat in sarcomas that share key characteristics of Ewing sarcoma; the potential of seclidemstat as a potential treatment for Ewing-related sarcomas; the expansion of Salarius' current clinical program; the ability of seclidemstat to demonstrate drug activity; the ability of and degree to which seclidemstat could have a significant impact on the treatment of Ewing sarcoma, as well as other sarcomas with related

Ewing sarcoma biology; and Salarius' ability to develop seclidemstat for broader patient populations.. 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 Salarius to raise additional capital to meet its business operational needs and to achieve its business objectives and strategy; Salarius' 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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