Salarius Pharmaceuticals Initiates Expansion Stage of Phase 1/2 Clinical Trial of Seclidemstat in Patients with Ewing Sarcoma and Ewing-Related Sarcomas

Relapsed and refractory Ewing sarcoma patients to receive seclidemstat in combination with chemotherapy agents as second- and third-line therapy; Protocol amendment expands and improves access to addressable patient population

Ewing-related sarcoma patients to receive single-agent therapy supported by preliminary signs of drug activity indicating an increase in patients time to progression

Salarius to host Conference Call and Live Audio Webcast Today, Wednesday, February 24, 2021, at 8:30 a.m. ET

HOUSTON, February 24, 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, announced today the initiation of the expansion stage of its ongoing Phase 1/2 clinical trial of seclidemstat in patients with relapsed and refractory (R/R) Ewing sarcoma and Ewing-related sarcomas, also known as FET-translocated sarcomas. Seclidemstat is a novel, oral, reversible inhibitor of the lysine-specific histone demethylase 1 enzyme (LSD1), an enzyme that has been shown to play a key role in the development and progression of certain cancers.

Per the amended trial protocol, the expansion stage will consist of two treatment arms. The first arm will enroll up to 20 Ewing sarcoma patients and will investigate seclidemstat at the recommended Phase 2 dose (RP2D) in combination with the chemotherapy agents topotecan and cyclophosphamide (TC) as a potential second- and third-line therapy for Ewing sarcoma. The second arm will enroll up to 30 patients with Ewing-related sarcomas and will investigate seclidemstat as a single-agent therapy at the RP2D. Both the Ewing and Ewing-related sarcoma arms are designed to evaluate safety and efficacy endpoints, and Salarius expects to report data readouts from the trial towards the end of 2021 and into 2022.

“Combining seclidemstat with the chemotherapy agents topotecan and cyclophosphamide, a well-accepted second- or third-line treatment for patients with Ewing sarcoma, provides an opportunity to utilize seclidemstat earlier in the treatment continuum while increasing the patient population that receives seclidemstat,” stated Damon Reed, M.D., Program Leader of the Adolescent and Young Adult Program at the Moffitt Cancer Center and Principle Investigator of the Salarius Ewing and Ewing-related sarcoma clinical trial.

Nadeem Q. Mirza, M.D., M.P.H., Senior Vice President, Clinical Development for Salarius, commented, “There is strong support for this development strategy. Safety data for seclidemstat from the previous dose-escalation stage of the Ewing sarcoma trial suggests that a combination regimen with topotecan and cyclophosphamide should result in a manageable safety profile, an important aspect when considering combination treatments for cancer patients. Moreover, internal preclinical research of seclidemstat in Ewing sarcoma cell lines showed seclidemstat to have an additive effect when combined with topotecan

and cyclophosphamide; meaning the anti-tumor effects of each therapy build upon each other and together have a more pronounced effect on Ewing sarcoma cells."

Dr. Mirza continued, "The expansion into Ewing-related sarcomas is supported by encouraging signs of seclidemstat clinical activity among the subset of Ewing-related sarcoma patients enrolled in our Advanced Solid Tumor trial. All of these patients had time to progression longer than a common benchmark used to assess single-agent activity in the advanced, relapsed soft tissue sarcoma setting. Furthermore, as previously reported, all patients in the subset demonstrated preliminary signs of seclidemstat drug activity at levels below the RP2D. Based on these results, Salarius has the opportunity to pursue a second treatable patient population and establish a potential second path to regulatory approval for seclidemstat."

"This is an exciting opportunity to strengthen the treatment alternatives we can deliver to patients and to expand the number of patients who may benefit from seclidemstat," stated David Arthur, President and Chief Executive of Salarius Pharmaceuticals. "By combining seclidemstat with topotecan and cyclophosphamide, we hope to open the door to seclidemstat's potential use earlier in the treatment continuum as second- and third-line therapy while improving outcomes for Ewing sarcoma patients. We believe our clinical program across Ewing and Ewing-related sarcomas allows more patients to receive seclidemstat far earlier in their treatment paradigm, and we believe this could not only increase the clinical benefits of seclidemstat but also provide the best chance to improve survival outcomes."

Ewing Sarcoma Dose-Escalation Trial Review

As previously announced, the recently completed dose-escalation stage of the Phase 1/2 trial demonstrated seclidemstat had a manageable safety profile and established the recommended Phase 2 dose (RP2D). Further, pharmacokinetic (PK) data from the dose-escalation study indicated that treatment at the RP2D achieved plasma concentrations above levels where seclidemstat demonstrated activity in preclinical studies.

Safety and efficacy results from both the Ewing sarcoma trial and the Advanced Solid Tumor trial are planned for presentation at an upcoming medical conference. Conference embargo rules prevent further disclosure at this time.

Conference Call Information:

Salarius Pharmaceuticals will host a conference call and live audio webcast on Wednesday, February 24, 2021, at 8:30 a.m. ET, to discuss advancements in the Phase 1/2 clinical trial of seclidemstat in patients with Ewing sarcoma and Ewing-related sarcomas. Interested participants and investors may access the conference call by dialing either:

- (833) 423-0481 (U.S.)
- (918) 922-2375 (international)
- Conference ID: 9278225

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, for which it has received Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation 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 the recipient of a 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 "anticipate," "potential," "progress," "design," "estimate," "continue," "will," "aim," "can," "believe," "plan," "allow," "expect," "intend," "goal," "provide," "able to," "position," "project," "developing," and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements relating to the following: The status and anticipated progress and milestones of Salarius' clinical trials in relapsed and refractory Ewing sarcoma and Ewing-related sarcomas; Salarius' developing cancer therapies for patients that need them the most; Salarius' developing seclidemstat for several cancers with high unmet medical need; Salarius' developing seclidemstat as a potential treatment for pediatric cancers, solid tumors and other cancers with limited treatment options; Salarius advancing seclidemstat to the dose-escalation stage of the Phase 1/2 clinical trial in relapsed and refractory Ewing sarcoma; the potential of seclidemstat as a treatment for Ewing-related sarcomas; the ability of seclidemstat to demonstrate drug activity; the ability and degree to which seclidemstat could have an impact on the treatment of Ewing sarcoma and Ewing-related sarcomas; the ability and degree to which seclidemstat administered in combination with the chemotherapy agents topotecan and cyclophosphamide could have an impact on the treatment of Ewing sarcoma. 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 sufficiency of Salarius' capital resources; the ability of, and need for, Salarius to raise additional capital to meet Salarius' business operational needs and to achieve its business objectives and strategy; Salarius' ability to project future capital needs and

cash utilization and timing and accuracy thereof; the ability of Salarius to access the remaining funding available under the CPRIT grant; future clinical trial results and impact of results on Salarius; 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 and regulatory or contractual restrictions which may impact the ability of Salarius to raise additional capital; the possibility of unexpected expenses or other uses of Salarius' cash resources; risks related to the COVID-19 outbreak; and other risks described in Salarius' filings with the Securities and Exchange Commission, including those discussed in Salarius' quarterly report on Form 10-Q for the quarter ended September 30, 2020 and in Salarius' annual report on Form 10-K for the year ended December 31, 2019. 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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