Salarius Pharmaceuticals Presents New Research Data Demonstrating Seclidemstat's Safety, Dosing, and Drug Activity at American Society of Clinical Oncology (ASCO) 2021 Annual Meeting

Presentations highlight full data from dose-escalation stage of Phase 1/2 clinical trial in Ewing sarcoma and interim data from Advanced Solid Tumor (AST) trial

Initial drug activity observed in both relapsed/refractory Ewing sarcoma and AST trials

Advanced FET-rearranged sarcoma patients in AST trial demonstrated stable disease and prolonged time to progression suggestive of disease control, a clinically relevant endpoint for soft tissue sarcomas

HOUSTON, June 7, 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, presented key findings from clinical research involving its lead drug candidate, seclidemstat. These results, disclosed in poster presentations at the American Society of Clinical Oncology (ASCO) Virtual Annual Meeting, included data on seclidemstat's safety, dosing and early efficacy signals in patients with Ewing sarcoma, a rare pediatric bone cancer, and other solid tumors, including FET-rearranged sarcomas. The ASCO Annual Meeting is taking place June 4-8, 2021.

Seclidemstat is a novel, oral, reversible inhibitor of the lysine-specific histone demethylase 1 (LSD1), an enzyme that has been shown to play a key role in the development and progression of several cancers.

In summary, data presented for the first time during ASCO demonstrated that seclidemstat has a manageable safety profile, favorable pharmacokinetics that support twice-daily oral dosing, and showed evidence of anti-tumor activity in an advanced, heavily pre-treated patient population. In addition, seclidemstat showed no significant hematological toxicities, which can be a limitation for other LSD1 inhibitors.

Importantly, single-agent seclidemstat treatment showed signs of drug activity in patients with relapsed/refractory Ewing sarcoma and other advanced cancers, including FET-rearranged sarcomas, also referred to as Ewing-related sarcomas. In patients with FET-rearranged sarcomas, seclidemstat treatment resulted in stable disease (SD) and prolonged time to progression (TTP) suggestive of disease control, a clinically relevant endpoint for soft tissue sarcomas.

"The ASCO presentations demonstrate what we expected to see during the dose-escalation portion of the ongoing clinical trials," stated David Arthur, Chief Executive Officer of Salarius Pharmaceuticals. "In addition to exhibiting drug activity across Ewing and Ewing-related sarcomas, seclidemstat demonstrated a manageable safety profile, a favorable pharmacokinetic profile, and importantly, single-agent drug activity in heavily pre-treated patients with very advanced sarcomas."

Damon Reed, M.D., Director of the Adolescent and Young Adult Program at Moffitt Cancer Center and Principal Investigator in the Ewing sarcoma trial, added, "The disclosed data support the continued development of seclidemstat in relapsed/refractory Ewing sarcoma and other advanced cancers, including FET-rearranged sarcomas. The amended clinical trial expands access to seclidemstat to additional, high-need FET-rearranged sarcoma patient populations, and as a combination therapy, enabling the drug's use earlier in the continuum of Ewing sarcoma care."

The full posters are available on ASCO's 2021 Meeting Library. Details from the poster presentations are as follows:

Poster Title: Phase 1 trial of seclidemstat (SP-2577) in patients with relapsed/refractory Ewing sarcoma (Abstract #11514)
Session Type & Title: Poster Discussion Session, Sarcoma
Date & Time: June 4, 2021, 9 a.m. ET
Key Information & Findings: For the first time, Salarius is discussing the full findings from the dose-expansion stage of the Phase 1/2, open label study of single-agent seclidemstat in patients with elapsed/refractory Ewing sarcoma. Seclidemstat demonstrated a manageable safety profile with proof-of-concept preliminary activity at or below the recommended Phase 2 dose (RP2D), established as 900 mg BID.

- In this heavily pretreated population, a patient dosed at 600 mg BID achieved a reduction in three target lesions after 58 days (2 cycles) with further tumor shrinkage after 112 days (4 cycles) and 168 days (6 cycles) for a maximum 76% tumor shrinkage despite overall progressive disease
- Two additional patients dosed at 600 mg BID and 900 mg BID for 56 days (2 cycles) demonstrated overall stable disease
- Seclidemstat's safety profile is predominantly GI-related with no treatment-related deaths and no significant hematological treatment-related adverse events (TRAEs)
- Study results warrant further study of seclidemstat in Ewing sarcoma combined with chemotherapy

Poster Title: Preliminary efficacy from an ongoing Phase 1 dose escalation of seclidemstat (SP-2577) in patients with advanced solid tumors (Abstract #3073)
Session Type & Title: Poster Session, Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Date & Time: Friday, June 4, 2021, 9 a.m. ET
Key Information & Findings: This is an ongoing Phase 1/2 open-label, dose-escalation trial assessing single-agent seclidemstat in advanced or recurrent solid tumors. As of April 13, 2021, seclidemstat demonstrated initial activity among advanced sarcoma patients with a manageable safety profile.

- 7 patients treated for ovarian cancer, prostate cancer and sarcomas achieved stable disease (SD) after 56 days (2 cycles) with median time to progression (TTP) of 4.3 months; patients with advanced FET-rearranged sarcomas demonstrated prolonged SD and prolonged TTP suggestive of disease control, a clinically relevant endpoint for soft tissue sarcoma
- As of April 13, 2021, 3 FET-rearranged sarcoma patients demonstrated TTP of 9.4 months, 7.2 months and 4.3 months, respectively

- Among 3 patients with FET-translocated sarcomas, prolonged SD greater than 6 months was observed in 2 patients (66%)
- An elderly patient treated for metastatic extra skeletal myxoid chondrosarcoma, with an aggressive TAF15-CHN translocation, who demonstrated overall SD for 9.4 months has continued therapy and has now been treated for 11 cycles

- All 3 FET-translocated patients enrolled in the study showed a TTP that suggests single-agent activity based on a benchmark used to assess novel agent activity for advanced soft tissue sarcomas (Van Glabbeke, 2004)
- Preliminary clinical data supports further exploration in FET-translocated sarcomas, or Ewing-related sarcomas, as a single agent and in a combination therapy

Poster Title: Phase 1 expansion trial of the LSD1 inhibitor seclidemstat (SP-2577) with and without topotecan and cyclophosphamide (TC) in patients (pts) with relapsed or refractory Ewing sarcoma (ES) and select sarcomas (Abstract #TPS11577)
Session Type & Title: Poster Session, Sarcoma
Date & Time: June 4, 2021, 9 a.m. ET
Key Information: This is an ongoing dose-expansion study assessing seclidemstat at the RP2D (900 mg BID) in two patient cohorts: a single-agent expansion in select sarcoma patients and a safety lead-in dose escalation and expansion of seclidemstat in combination with the chemotherapy agents topotecan and cyclophosphamide (TC) in Ewing sarcoma patients.

- The sarcoma cohort will enroll patients with myxoid liposarcoma or other select sarcomas with FET family translocations, including desmoplastic small round cell tumor (DSRCT); the trial will enroll patients treated with one to three prior lines of therapy
- The Ewing sarcoma cohort will allow patients treated with up to two prior lines of therapy
- Primary objective is safety and tolerability, and secondary objective is efficacy
- Recruiting patients across eight U.S. locations

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 select additional sarcomas that share a similar biology to Ewing sarcoma, also referred to as Ewing-related or FET-rearranged sarcomas. Seclidemstat has received Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation for 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 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 company's growth strategy; the value of seclidemstat as a potential treatment for Ewing sarcoma, Ewing-related sarcomas and other cancers; the status and anticipated progress and milestones of the company's clinical trials in Advanced Solid Tumors and Ewing sarcoma; the expansion of the company's clinical trials to include Ewing-related sarcomas; the company's belief as to being well-capitalized through the completion of its clinical trials for seclidemstat and beyond; Salarius' goal to maximize the potential of seclidemstat; and Salarius developing seclidemstat for several cancers with high unmet medical need. 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 the company's capital resources; the ability of, and need for, 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 and timing and accuracy thereof; the ability of the company to access the remaining funding available under the CPRIT grant; future clinical trial results and impact of results on the company; 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 the company's quarterly report on Form 10-Q for the quarter ended March 31, 2021 and in the company's annual report on Form 10-K for the year ended December 31, 2020. 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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