Salarius Pharmaceuticals Discloses Key Findings from Three Abstracts to be Presented at American Society of Clinical Oncology (ASCO) 2021 Annual Meeting

Preliminary drug activity observed in both relapsed/refractory Ewing sarcoma and Advanced Solid Tumor (AST) trials

Presentations include full data from dose-escalation stage of Phase 1/2 clinical trial evaluating seclidemstat in Ewing sarcoma and preliminary data from ongoing AST trial

HOUSTON, May 19, 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 publication by the American Society of Clinical Oncology (ASCO) of three abstracts accepted for poster presentations during the ASCO 2021 Annual Meeting. ASCO 2021 will take place June 4-8, 2021 via a virtual platform.

Salarius submitted three abstracts disclosing clinical research involving its lead drug candidate, seclidemstat. Details on the presentations can be found below. Key findings include data showing that seclidemstat has a manageable safety profile with no significant hematological toxicities, which can be a limitation for other LSD1 inhibitors. In addition, seclidemstat showed proof-of-concept preliminary drug activity in relapsed/refractory Ewing sarcoma and other advanced cancer patients, including FET-rearranged sarcomas, at or below the recommended phase 2 dose (RP2D), which was established to be 900 mg BID.

“We are excited to have the opportunity to present clinical data regarding safety, dosing, and initial efficacy signals for seclidemstat during ASCO 2021,” said David Arthur, President and Chief Executive of Salarius Pharmaceuticals. “For the first time, we will report full data and the recommended Phase 2 dose from the recently completed dose-escalation stage of our Phase 1/2 clinical trial in Ewing sarcoma. We will also discuss in more detail the preliminary drug activity data observed in FET-rearranged sarcoma patients from our Advanced Solid Tumor (AST) trial that supports our continued development of seclidemstat as single-agent therapy in select sarcomas.”

The full abstracts are available on ASCO’s 2021 Meeting Library. Details from the Salarius abstracts are as follows:

Abstract #11514: Phase 1 trial of seclidemstat (SP-2577) in patients with relapsed/refractory Ewing sarcoma
Session Type & Title: Poster Discussion Session, Sarcoma
Presenting Author: Damon R. Reed, M.D., H. Lee Moffitt Cancer Center & Research Institute, Tampa, Florida.
Date & Time: June 4, 2021, 9 a.m. ET
Key Information & Findings: Seclidemstat has a manageable safety profile with proof-of-concept preliminary activity in heavily pretreated patients with relapsed or refractory Ewing sarcoma.

- 900 mg BID established as the RP2D
- A patient dosed at 600 mg BID achieved a reduction in target lesions after 58 days (cycle 2) with further tumor shrinkage after 112 days (cycle 4) and 168 days (cycle 6) for a maximum 76% tumor shrinkage; Coincident new non-target lesion appearance at end of cycle 2
- Two additional patients dosed at 600 mg BID and 900 mg BID had overall stable disease
- No treatment-related deaths; The most common (>5%) Grade 3 treatment-related adverse events (TRAEs) were vomiting (15%), abdominal pain (11%), and hypokalemia (11%); One patient with Grade 3 pancreatitis reported elevated lipase, a Grade 4 adverse event (AE); No significant hematological TRAES (Grade 3 occurred in <5% of patients)

Abstract #3073: Preliminary efficacy from an ongoing phase 1 dose escalation study of seclidemstat (SP-2577) in patients (pts) with advanced solid tumors (AST)
Session Type & Title: Poster Session, Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Presenting Author: Sant P. Chawla, M.D., Sarcoma Oncology Research Center, Santa Monica, California
Date & Time: Friday, June 4, 2021, 9 a.m. ET
Key Information & Findings: Seclidemstat has shown activity among advanced sarcoma patients with a manageable safety profile. Dose escalation is ongoing and preliminary clinical data supports further exploration in FET-translocated sarcomas as single agent and in combination therapy. Safety data will be presented after completion of Phase 1 dose-escalation.

- As of December 30, 2020, 19 patients were enrolled in AST trial, including patients with prostate ovarian, pancreatic, renal, cervical and breast cancer, as well as sarcomas; Patients received a median of four prior systemic treatments
- 13 patients were evaluable for response after 58 days of treatment (cycle 2); 7 patients had best response of stable disease (SD) with median time to progression (TTP) of 4.3 months, including 3 patients with advanced FET-rearranged sarcomas
- All 7 patients were dosed at 300 mg BID or 600 mg BID
- The most common Grade 3 TRAEs were gastrointestinal-related and included diarrhea (5.3%) and abdominal pain (5.3%)
- No treatment-related deaths and no Grade 4 TRAEs have been reported

Abstract #TPS11577: 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
Session Type & Title: Poster Session, Sarcoma
Presenting Author: Damon Reed, M.D., H. Lee Moffitt Cancer Center & Research Institute, Tampa, Florida.
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 cohorts: a single-agent expansion in select sarcoma patients and a safety lead-in dose escalation and expansion of seclidemstat in combination with 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 allow 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

This year, ASCO received and reviewed more than 5,400 abstracts for the 2021 Annual Meeting, the world's largest gathering of physicians, biopharmaceutical companies, researchers, and investors to discuss cancer research and therapeutics. Information about the Annual Meeting may be accessed at https://conferences.asco.org/am/registration.

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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