



Salarius Pharmaceuticals to Present Trial in Progress Poster at ASCO20 Virtual Scientific Program

Patient Enrollment Continues in Phase 1/2 Dose Escalation Trial for Seclidemstat in Relapsed or Refractory Ewing Sarcoma

HOUSTON, May 27, 2020 (GLOBE NEWSWIRE) -- Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biotechnology company targeting cancers caused by dysregulated gene expression, today announced that a Trial in Progress poster of the ongoing Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma will be presented during the 2020 American Society of Clinical Oncology Virtual Scientific Program (ASCO20 Virtual). The poster describes the trial's design and highlights important dose escalation enrollment advances achieved during the past year.

Details of the presentation are as follows:

Title: A phase I/II clinical trial of the reversible LSD1 inhibitor, seclidemstat, in patients with relapsed/refractory Ewing sarcoma

Date and Time: Friday, May 29, 2020, 8 a.m. ET (Oral, Poster Discussion, and Poster Sessions, as well as track-based Clinical Science Symposia, will be available on demand)

Abstract Number: TPS11567

Poster Number: 455

Session: Sarcoma

Designed as an open-label, non-randomized dose-escalation/dose-expansion study, the primary objective of the Phase 1/2 clinical trial is to assess seclidemstat's safety and tolerability in patients with relapsed or refractory Ewing sarcoma. Secondary objectives include studying the pharmacokinetics and assessing preliminary anti-tumor activity of seclidemstat. Exploratory objectives include collecting potential pharmacodynamic markers to study drug activity and disease burden.

As reported recently, the Safety Review Committee overseeing the Ewing sarcoma clinical trial approved the advancement of the study to the sixth dosing cohort (1,200mg BID) out of seven potential cohorts, patient enrollment is ongoing, and, to date, we have not seen dose limiting toxicities that would prevent further dose escalation. Thus far, pharmacokinetic data from the trial suggest that plasma drug levels of the first five cohorts are increasing in a dose proportional manner and there is no evidence of a plateau in exposure levels. Also recently reported, seclidemstat plasma levels in patients are now at or above the levels where pharmacological activity was observed in pre-clinical studies. Based on current projections, Salarius believes the Phase 1/2 Ewing sarcoma trial is on track to reach maximum tolerated dose (MTD) in 2020, and shortly after, begin the dose-expansion phase of the study. Salarius expects to report early safety and pharmacokinetic data before year-end 2020.

"We are very appreciative of the ongoing efforts of the investigators involved in our Phase 1/2 clinical trial of seclidemstat in Ewing sarcoma and are grateful for the opportunity to present this Trial in



Progress poster during ASCO20 Virtual,” stated David Arthur, President and CEO of Salarius. “Ewing sarcoma is a rare and deadly bone cancer that most often strikes children and young adults. The continued progress of this study, despite the challenges resulting from the COVID-19 outbreak, has demonstrated the tremendous dedication and resilience of our investigators and the patients and families who have volunteered to participate.”

About Salarius Pharmaceuticals, Inc.

Salarius Pharmaceuticals, Inc. is a clinical-stage oncology company targeting cancers caused by dysregulated gene expression 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 (Phase 1/2 trial) for treating 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 a number of cancers, with a second Phase 1/2 clinical study targeting 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,” “expect,” “target,” “potential,” “objective,” and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements related to the following: the anticipated presentation of the Trial in Progress Poster of the ongoing Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma; the trial’s design; the objectives of Salarius’ Phase 1/2 clinical trial to assess seclidemstat’s safety and tolerability in patients with relapsed or refractory Ewing sarcoma and to study the pharmacokinetics and assess preliminary anti-tumor activity of seclidemstat; Salarius’ belief that the Phase 1/2 Ewing sarcoma trial is on track to reach maximum tolerated dose in 2020 and that the dose-expansion phase of the study may occur shortly thereafter; and Salarius’ expectations regarding the reporting of early safety and pharmacokinetic data before year-end 2020. 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; 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 sell stock to Aspire 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, 2020 and in the company's 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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