Salarius Pharmaceuticals Adds Fox Chase Cancer Center to Ongoing Trial of Seclidemstat as a Treatment for Ewing Sarcoma and FET-Rearranged Sarcomas

Clinical Trial Now Expands to Nine U.S. Trial Sites

HOUSTON, July 13, 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 that Fox Chase Cancer Center in Philadelphia, PA, has been added as an active trial site for the dose-expansion stage of the ongoing clinical trial evaluating the company's lead drug candidate, seclidemstat, in patients with relapsed or refractory Ewing sarcoma and advanced FET-rearranged sarcomas.

The addition of Fox Chase expands to nine the number of active sites participating in the open label trial intended to assess seclidemstat at the recommended Phase 2 dose (RP2D). Patient recruitment is now underway at all sites, and the first patients in the dose-expansion stage of the clinical trial have been dosed.

Seclidemstat is a novel, oral, reversible inhibitor of 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.

Per the amended protocol, the trial's dose-expansion stage now includes three patient arms. The first arm will enroll up to 30 patients with Ewing sarcoma, a rare and deadly pediatric bone cancer, and will investigate seclidemstat in combination with topotecan and cyclophosphamide, a commonly used second- and third- line chemotherapy regimen. Salarius believes data released during ASCO 2021 demonstrated synergy in an Ewing sarcoma cell line when seclidemstat was used in combination with topotecan and cyclophosphamide. Salarius believes this treatment combination and its use as a second- and third-line therapy could greatly expand the addressable patient population for seclidemstat and improve outcomes by allowing physicians to use seclidemstat earlier in the Ewing sarcoma continuum of care.

The trial's second patient arm will investigate seclidemstat as a single agent in up to 15 patients with myxoid liposarcoma. The third patient arm will investigate seclidemstat as a single agent in up to 15 patients with select sarcomas that share a biology similar to Ewing sarcoma, also referred to as FET-rearranged or Ewing-related sarcomas. In data released at ASCO 2021, a subset of patients with advanced FET-rearranged sarcomas treated with single-agent seclidemstat resulted in stable disease (SD) and prolonged time to progression (TTP) which Salarius believes suggests disease control, a clinically relevant endpoint for soft tissue sarcomas.

All patient arms are designed to evaluate safety and efficacy endpoints in patients with advanced disease. Salarius expects to report data in 2022 and provide earlier updates if possible.

"We are excited to be working with Salarius and look forward to exploring the potential of seclidemstat and its ability to inhibit the LSD1 enzyme," stated Johnathan Whetstine, Ph.D., Director, Cancer

Epigenetics Institute, Fox Chase Cancer Center. “Based on our extensive research into the epigenetic causes of cancer, we believe LSD1 inhibition holds great promise in the treatment of many cancers. We believe data from preclinical studies using Ewing sarcoma cell lines has demonstrated the molecule’s ability to hit two aspects of the enzyme simultaneously. This, added to clinical data showing drug activity across Ewing and other sarcomas, support the further exploration of seclidemstat in these high unmet need patient populations.” Dr. Whetstine is a consultant to Salarius and has also served in an advisory capacity.

David Arthur, CEO of Salarius Pharmaceuticals, stated, “Our goal is to make a difference in the lives of patients fighting cancer, and we believe the data we have released to date has been compelling. To now be working with a cancer research center of the caliber of Fox Chase Cancer Center further affirms the potential of seclidemstat to have a meaningful impact on the treatment of Ewing sarcoma and other cancers. We look forward to providing additional updates throughout 2021.”

Trial enrollment at Fox Chase will be led by Margaret von Mehren, M.D., Chief of Sarcoma Oncology.

In addition to Fox Chase, active clinical trial site locations include, Johns Hopkins All Children’s Hospital in St. Petersburg, FL; Children’s Hospital of Los Angeles in Los Angeles, CA; Moffitt Cancer Center in Tampa, FL; Dana-Farber Cancer Institute in Boston, MA; MD Anderson Cancer Center in Houston, TX; Nationwide Children’s Hospital in Columbus, OH; Memorial Sloan Kettering Cancer Center in New York City; and the Sarcoma Oncology Center in Santa Monica, CA.

About Fox Chase Cancer Center

The Hospital of Fox Chase Cancer Center and its affiliates (collectively “Fox Chase Cancer Center”), a member of the Temple University Health System, is one of the leading cancer research and treatment centers in the United States. Founded in 1904 in Philadelphia as one of the nation’s first cancer hospitals, Fox Chase was also among the first institutions to be designated a National Cancer Institute Comprehensive Cancer Center in 1974. The recently founded Cancer Epigenetics Institute is a national hub for epigenetics study and collaboration focused on mechanisms promoting cancer and therapeutic resistance. Its mission is to facilitate academic-to-industry and academic-to-academic partnerships with the goal of promoting discovery in cancer epigenetics. Fox Chase researchers have won the highest awards in their fields, including two Nobel Prizes. Fox Chase physicians are also routinely recognized in national rankings, and the Center’s nursing program has received the Magnet recognition for excellence five consecutive times. Today, Fox Chase conducts a broad array of nationally competitive basic, translational, and clinical research, with special programs in cancer prevention, detection, survivorship and community outreach. It is the policy of Fox Chase Cancer Center, that no one shall be excluded from or denied the benefits of or participation in the delivery of quality medical care on the basis of race, ethnicity, religion, sexual orientation, gender, gender identity/expression, disability, age, ancestry, color, national origin, physical ability, level of education, or source of payment.

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 ability to enroll patients in any arm of the current clinical trials; the value and efficacy of seclidemstat, either by itself or together with other products, as a therapy in any indication; the status and anticipated progress and milestones of the company's clinical trials; the anticipated readout of clinical trial results; the expansion of the company's clinical trials; 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 are 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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