Salarius Pharmaceuticals CEO Issues Letter to Stockholders

HOUSTON, Aug. 12, 2019 (GLOBE NEWSWIRE) -- (Nasdaq: SLRX), a clinical-stage oncology company targeting the epigenetic causes of cancers, today announced that its chief executive officer, David Arthur, issued an open letter to Salarius' stockholders following the completion of the reverse merger with Flex Pharma, Inc. The following letter can also be viewed on Salarius' website.

Dear Stockholder,

We are thrilled to have completed the merger with Flex Pharma and to have begun trading on Nasdaq with the new trading symbol "SLRX". This represents the culmination of many years of hard work, dedication, and innovation from talented people, and we are proud of what we have accomplished.

Following the reverse merger, Salarius' stockholder base is now comprised of a combination of former Flex Pharma stockholders, former unit holders of Salarius Pharmaceuticals, LLC, and new stockholders. The purpose of this letter is to provide each of you with an overview and update on Salarius Pharmaceuticals, Inc. and our plan for building stockholder value by advancing clinical programs.

Salarius' development trajectory is on course and we look forward to your support as we work toward developing novel treatments for patients who need them the most. We believe in our science, vision and clinical programs that are poised to generate data validating our approach. Additionally, prior to entering into the merger agreement with Flex Pharma, our technology, pipeline, clinical plan, market opportunity, finances, and management team were reviewed carefully by Flex Pharma. Flex Pharma selected Salarius based on due diligence and discussions with nearly 40 other companies, which we believe provides substantial third-party validation for our business.

In short, Salarius is a cancer-focused biotechnology company developing treatments for patients who need them the most. Today, that includes active clinical development programs dedicated to delivering new therapeutic options for:

- Patients with Ewing Sarcoma, a rare and devastating bone and soft-tissue cancer that mostly afflicts children and young adults for which no approved targeted therapies are currently available. Unfortunately, the standard of care treatment for these children and young adults currently is adult chemotherapy, radiation and often disfiguring surgeries.
- Patients with advanced solid tumors, such as prostate, breast, and ovarian cancers who have not responded to or are no longer responding to standard of care treatments and are seeking new potential treatments.

Our lead drug candidate or potential medicine, Seclidemstat, is an oral tablet with a targeted, disease-specific mechanism of action, unlike toxic chemotherapy.

Our technology targets the epigenetic causes of cancer. Epigenetics is the study of the regulatory system that controls how genes are turned "on" or "off." In certain cancers, the proteins that regulate gene expression become dysregulated and incorrectly turn genes "on" or "off," which in some cases leads to cancer progression. Drugs that are able to safely modify the activity of these epigenetic regulators may correct the gene changes that are driving the disease. The field of epigenetics is maturing, and with a differentiated drug candidate in two clinical studies, Salarius has the potential to become a leader in this exciting area of cancer research.

The Food and Drug Administration (FDA) has already granted our lead drug candidate, Seclidemstat, both Orphan Drug and Rare Pediatric Disease designations, conferring certain regulatory benefits and commercial advantages upon a potential FDA approval. If proven efficacious with a benefit-risk profile that the FDA judges to be positive and supportive of approval, Seclidemstat could qualify to receive a pediatric priority review voucher (PRV), which the FDA awards to companies developing a drug or biologic that targets a rare pediatric disease. If received, this voucher adds significant value to our Seclidemstat program. PRVs can be sold to other qualifying companies and based on 2017-2018 selling prices, a PRV has a value ranging between $80 million and $150 million.

Our Ewing Sarcoma program is progressing in a Phase 1 clinical trial that is currently in the dose escalation phase, and we expect to establish the maximum tolerable dose (MTD) in early-2020. We then expect to commence dose expansion with the potential for reporting early cohort data later in 2020.

We are also developing Seclidemstat for adults with advanced solid tumor cancers. We recently began enrolling a Phase 1 dose escalation/dose expansion study in advanced solid tumors, including but not limited to, breast, ovarian and prostate cancer patients. Early cohort data readouts are also expected in 2020.

Importantly, in 2016, Salarius was granted a $18.7 million Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT), of which approximately $11.8 million remains available to Salarius. This funding, which does not dilute investor equity holdings, has enabled us to move our programs forward. In addition, the National Pediatric Cancer Foundation (NPCF) provides financial support funding our Ewing sarcoma clinical trial. This NPCF funding also does not dilute investor equity holdings.

We are committed to advancing Seclidemstat toward potential FDA and global approval. Our team of scientists, clinicians, and other professionals, as well as our Board of Directors and Scientific Advisors are dedicated to this effort and to the opportunity to improve patients' lives. In addition, Salarius' executive officers and Board members, and certain executive officers,

directors and stockholders of Flex Pharma (prior to the merger), agreed to a 90-day restriction on sales by them of the company's shares. We see great potential for Seclidemstat, for our clinical pipeline, and for our ability meet the unmet medical needs of patients.

In terms of upcoming financial disclosures, we plan to file a Form 8-K/A within the next few months that will contain certain interim and pro forma financial information relating to the merger of the two companies. Going forward, we will report our quarterly and year-end financial results, as required, on a typical filing schedule for public companies, including our results for the third quarter ended September 30, 2019.

We believe stockholder value is created by reporting clinical data showing patient benefit in response to Seclidemstat. To that end, our timeline for releasing clinical data and reaching possible inflection points is largely unchanged. In June 2019, Salarius was a private company executing a clinical plan to potentially report early patient cohort data in 2020. Two months later, we are a public company listed on Nasdaq executing that same clinical plan to potentially report early patient cohort data in 2020.

Our top priority is the continued execution of our clinical trials and as such, patient enrollment and efficient clinical operations remain our top focus. We look forward to providing updates on our progress and we invite you to visit our website at for more information.

We thank you for your current support and for your continued support as we strive to deliver maximum value for you, our stockholder, and deliver potential new medicines for the many patients and their families fighting cancer.

Best regards,

David Arthur
Chief Executive Officer

About Salarius Pharmaceuticals

Salarius Pharmaceuticals, LLC is a clinical-stage oncology company targeting the epigenetic

causes of cancers and is developing treatments for patients that need them the most. The company's lead candidate, Seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has Orphan Drug designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. Salarius believes that Seclidemstat is one of only two reversible inhibitors of the epigenetic modulator LSD1 currently in human trials, and that it could have potential for improved safety and efficacy compared to other LSD1-targeted therapies. Salarius is also developing Seclidemstat for a number of cancers with high unmet medical need, with an ongoing clinical study in Ewing sarcoma and a clinical study in advanced solid tumors, including prostate, breast and ovarian cancers. Salarius receives financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and is also the recipient of an $18.7 million Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit .

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. Examples of such statements include, but are not limited to, statements relating to: the potential for Seclidemstat to target the epigenetic dysregulation underlying Ewing sarcoma and advanced solid tumors including, but not limited to, prostate, breast, and ovarian cancers; expected timing and results of clinical studies; Salarius' development trajectory; third-party validation for Salarius' business; changes in the field of epigenetics and Salarius' potential in such field; the likelihood of Seclidemstat qualifying to receive a pediatric priority review voucher (PRV) and the potential value of such PRV; Seclidemstat's FDA and global approval and expected benefits and advantages upon obtaining FDA approval; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. 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 ability of 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; future clinical trial results; 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; and the competitive landscape and other industry-related risks. 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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