Salarius Pharmaceuticals Reports First Quarter 2020 Financial Results

Seclidemstat Advances Dose Escalation in Phase 1/2 Ewing Sarcoma Clinical Trial; On Track to Report Early Data in 2020

Conference Call and Live Audio Webcast Scheduled for Today, May 14, 2020, at 4:30 p.m. ET

HOUSTON, May 14, 2020 (GLOBE NEWSWIRE) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biotechnology company targeting cancers caused by dysregulated gene expression, today reported its corporate and financial results for the first quarter ended March 31, 2020.

Financial Highlights:

- Closed $11 million gross proceeds in an underwritten public offering
- Three-month period ended March 31, 2020 net loss per common share – basic and diluted - for continuing operations of $0.22, compared to $0.64 for the same period ended March 31, 2019
- Total cash and cash equivalents of $9.65 million as of March 31, 2020
  - Up to $9.10 million remains available to draw from the Cancer Prevention and Research Institute of Texas (CPRIT) Award, upon meeting certain requirements
  - National Pediatric Cancer Foundation (NPCF) continues to provide significant funding for Ewing sarcoma study

Recent Business and Corporate Highlights:

- Phase 1/2 clinical study of seclidemstat in Ewing sarcoma advanced into the sixth level dosing cohort with Maximum Tolerated Dose (MTD) expected to be reached in mid-2020
- Scientific paper published highlighting potential of combining seclidemstat with cancer immunotherapies
  - In vitro data shows that seclidemstat helps overcome tumor resistance to checkpoint inhibitors
- European Patent Office (EPO) issued a notice of allowance for Patent EP274430 for seclidemstat
- William “Bill” McVicar, Ph.D., named as new Chairman of the Board of Directors

“Salarius is anticipating the potential for multiple clinical data releases and value building events throughout 2020 and beyond,” said David Arthur, President and CEO of Salarius. “Our clinical programs for seclidemstat continue to progress, and in the first quarter, we advanced dose-escalation in our Phase 1/2 clinical trial of seclidemstat in Ewing sarcoma. We eagerly anticipate releasing data from both the Ewing sarcoma clinical trial and our second clinical trial in advanced solid tumors (AST) in 2020.”

Mr. Arthur continued, “Salarius has worked to adapt to the unexpected and challenging circumstances resulting from the COVID-19 pandemic. At this time, we are experiencing minimal COVID-19 disruptions to our ongoing clinical programs and continue to enroll patients in our clinical trials.”

Mr. Arthur concluded, “Our goal is to maximize the potential of seclidemstat and bring hope to patients fighting rare, pediatric and other cancers. To that end, Salarius is well-capitalized and has the resources, including $9.1 million in non-dilutive funding that remains available from the 2016 $18.7 million CPRIT award, that we believe will advance both our Ewing sarcoma and AST programs, as well as early research on the potential for combining seclidemstat with immunotherapies, well into 2021.”

Three-Month Financial Results:
For the three-month period ended March 31, 2020, Salarius’ reported net loss was $2.08 million, or $0.22 per basic and diluted share, compared to a net loss of $1.52 million, or $0.64 per basic and diluted share for the same period in 2019. The loss before other income for the three-month period ended March 31, 2020 increased by $0.84 million compared to the loss before other income for the same time span last year, which was primarily due to an increase of $0.94 million in research and development expenses resulting from increased clinical trial expenses and drug manufacturing costs. Salarius also reported a net increase of $0.37 million in general and administrative costs resulting from Salarius’ transformation into a public company and increased personnel expenses during the current quarter, somewhat offset by lower professional fees and legal costs compared to same period in 2019.

As of March 31, 2020, total cash, cash equivalents and restricted cash was $9.65 million, compared to $5.77 million as of March 31, 2019 and $3.74 million at year-end 2019.

$11 Million Underwritten Public Offering
On February 11, 2020, Salarius completed a public offering with total gross proceeds of approximately $11 million, prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius. Salarius intends to use the net proceeds from the offering for general working capital purposes.

Summary of Corporate and Operational Events:

Ewing Sarcoma Dose Escalation Clinical Trial Advances into Sixth Dosing Cohort
Salarius is conducting two Phase 1/2 clinical trials for the company’s lead investigational drug candidate, seclidemstat – one in patients with relapsed or refractory Ewing sarcoma and the second in patients with advanced solid tumors (AST) resistant to standard-of-care therapies. The trials are designed as open-label dose-finding studies with a primary objective to characterize the pharmacokinetics (PK), Maximum Tolerated Dose (MTD), and initial safety profile of seclidemstat and a secondary objective to assess the preliminary efficacy.

In Q1 2020, 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, and patient enrollment is ongoing. Thus far, PK data from the trial suggest that plasma drug levels measuring the concentration of seclidemstat in a patient’s plasma remain dose proportional and there is no evidence of a plateau in exposure levels.

Dose escalation continues with the Phase 1/2 clinical trial in AST, which is now in the fourth dosing cohort (600mg BID) out of seven possible cohorts. The AST study enrolls patients with a focus on prostate, breast, ovarian, melanoma, colorectal, non-Ewing sarcomas and other cancers where seclidemstat demonstrated single-agent preclinical activity.

Based on current projections, Salarius believes both clinical trials are on track to reach MTD in 2020, and shortly after, begin the dose-expansion phase of each study. Salarius expects to report early safety and pharmacokinetic data before year-end 2020.

Scientific Paper Highlights Use of Seclidemstat in Combination with Checkpoint Inhibitors

Salarius is exploring additional indications for seclidemstat to expand the drug's market potential, and this includes seclidemstat's potential for use in combination with a type of cancer immunotherapy commonly known as checkpoint inhibitors. Checkpoint inhibitors, estimated at $15 billion in annual global sales, are designed to unleash an immune attack on cancer cells. However, these therapies do not work in about 70% of cancer patients, and in patients who do show an initial response, many suffer a return of the disease.

On February 4, 2020, a scientific paper entitled, "The Novel Reversible LSD1 Inhibitor SP-2577 Promotes Anti-Tumor Immunity in SWItch/Sucrose-NonFermentable (SWI/SNF)1," was published on bioRxiv.com. The paper highlighted data from in vitro studies conducted by Sunil Sharma, M.D., Salarius' scientific founder, and his team at the Translational Genomic Institute (TGen) in Phoenix, Ariz., that demonstrate the potential for seclidemstat (also known as SP-2577) to be used in combination with checkpoint inhibitors to treat cancers with identifiable mutations in proteins of the SWI/SNF complex. In this study, seclidemstat modulated the tumor microenvironment to help overcome the resistance to checkpoint inhibitors

The SWI/SNF complex plays an important role in modulating gene expression, and mutations in proteins of the SWI/SNF complex occur in roughly 20% of human cancers. In this study, Dr. Sharma's team investigated the ability of seclidemstat to promote anti-tumor immunity and T-cell infiltration in two types of ovarian cancer – small cell carcinoma of the ovary hypercalcemic type and ovarian clear cell carcinoma -- that both carry mutations in proteins of the SWI/SNF complex.

Salarius Strengthens IP Portfolio Around Seclidemstat

On March 4, 2020, Salarius announced the continued enhancement of the U.S. and global intellectual property (IP) portfolio governing seclidemstat. The European Patent Office issued a notice of allowance for Patent EP274430 exclusively licensed to Salarius from the University of Utah Research Foundation indicating that the agency is satisfied that the patent application meets all EPO requirements.

In all, Salarius holds 22 issued patents in the U.S. and abroad. The company's current IP estate includes five patents issued in the U.S. and another 17 patents issued in Europe, Australia, Brazil, China, Eurasia, Israel, India, Japan, Korea, Mexico, New Zealand, Singapore, and South Africa. Meanwhile, Salarius has 11 patent applications pending approval in Europe, Brazil, Canada, Israel, India, Korea, Mexico, Singapore,

and China. All 22 issued patents and the 11 pending applications are directed to seclidemstat or structurally similar compounds.

Salarius Names New Chairman of the Board
On April 29, 2020, Salarius announced that Board member William "Bill" McVicar, Ph.D., was named by the Board as its new Chairman. Dr. McVicar is a seasoned pharmaceutical industry executive with more than 30 years of clinical development experience. He recently served as Chief Executive Officer of Flex Pharma, and previously served as Chief Scientific Officer and President at Inotek Pharmaceuticals.

Conference Call Information:
Salarius Pharmaceuticals will host a conference call and live audio webcast on Thursday, May 14, 2020, at 4:30 p.m. ET, to discuss its corporate and financial results for the first quarter 2020. Interested participants and investors may access the conference call by dialing either:

- (833) 423-0481 (U.S.)
- (918) 922-2375 (international)
- Conference ID: 6281273

An audio webcast will be accessible via the Investors Events and Presentations section of the Company's website http://investors.salariuspharma.com/. An archive of the webcast will remain available for 90 days beginning at approximately 6:00 p.m. ET, on May 14, 2020.

About Salarius Pharmaceuticals
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 a Phase 1/2 clinical trial for 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 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 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 salariuspharma.com.

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," and

similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements relating to the following: Salarius' anticipation of the potential for multiple clinical data releases and value building events throughout 2020 and beyond; the anticipated progress of Salarius' clinical programs for seclidemstat; the anticipated release of data from both the Ewing sarcoma clinical trial and Salarius' second clinical trial in advanced solid tumors (AST) in 2020; the availability of funds available from CPRIT and NPCF; expectations as to the impact of the COVID-19 pandemic on the company's business and Salarius' enrollment of patients in clinical studies; Salarius' goal to maximize the potential of seclidemstat; Salarius' belief that it is well-capitalized with the resources to advance its Ewing sarcoma and AST programs, as well as early research on the potential for combining seclidemstat with immunotherapies, well into 2021; the intended use of proceeds from its recent public offering; the status (including with respect to patient enrollment), design, conduct, and objectives of Salarius' two Phase 1/2 clinical trials for seclidemstat; Salarius' belief, based on current projections, that both clinical trials are on track to reach MTD in 2020, and shortly after, begin the dose-expansion phase of each study; Salarius' anticipated reporting of early safety and pharmacokinetic data before year-end 2020; Salarius' exploration of additional indications for seclidemstat to expand the drug's market potential, including seclidemstat's potential for use in combination with checkpoint inhibitors; the estimated global sales of $15 billion for checkpoint inhibitors which are designed to unleash an immune attack on cancer cells; and the company's IP portfolio around seclidemstat.. 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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SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 9,646,940	$ 3,738,900
Grants receivable from CPRIT	591,129	—
Prepaid expenses and other current assets	646,360	955,899
Total current assets	10,884,429	4,694,799
Property and equipment, net	21,889	25,016
Goodwill	8,865,909	8,865,909
Other assets	293,147	308,674
Total assets	$ 20,065,374	$ 13,894,398
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 979,823	$ 1,790,966
Accrued expenses and other current liabilities	795,567	160,783
Note payable	252,679	502,332
Deferred revenue	—	541,701
Warrant liability	34,692	317,762
Total liabilities	2,062,761	3,313,544
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; 468,694 issued and outstanding	47	—
Common stock, $0.0001 par value; 100,000,000 shares authorized; 13,650,838 and 4,519,533 shares issued at March 31, 2020 and December 31, 2019, and 13,645,677 and 4,511,174 shares outstanding at March 31, 2020 and December 31, 2019, respectively	1,364	451
Additional paid-in capital	32,161,718	22,657,103
Accumulated deficit	(14,160,516)	(12,076,700)
Total stockholders' equity	18,002,613	10,580,854
Total liabilities and stockholders' equity	$ 20,065,374	$ 13,894,398

SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Revenue:		
Grant revenue	$ 1,132,830	$ 655,635
Operating expenses:		
Research and development	1,643,371	699,929
General and administrative	1,859,017	1,488,490
Total operating expenses	3,502,388	2,188,419
Loss before other income (expense)	(2,369,558)	(1,532,784)
Change in fair value of warrant liability	283,070	—
Interest income net	2,672	10,708
Net loss	**$ (2,083,816)**	**$ (1,522,076)**
Loss per common share — basic and diluted	**$ (0.22)**	**$ (0.64)**
Weighted-average number of common shares outstanding — basic and diluted	9,534,842	2,372,940