HOOKIPA Pharma Reports First Quarter 2019 Financial Results and Recent Business Highlights

May 20, 2019

NEW YORK and VIENNA, Austria, May 20, 2019 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (“HOOKIPA”), a company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform, today reported recent business highlights and financial results for the first quarter ended March 31, 2019.

“HOOKIPA’s achievements since the start of 2019 have demonstrated our ability to execute and deliver on key company goals. We reached the first milestones of our collaborative HIV and Hepatitis B programs with Gilead, further validating our technology in the area of infectious diseases. Our Series D financing in February and our initial public offering in April allowed us to continue to expand our strong shareholder base. Also, we now have the financial strength to achieve major milestones on our journey to translate great science into clinical programs. We continue to deliver on our mission to reprogram the immune system to fight severe infectious diseases and cancer,” said Joern Aldag, HOOKIPA’s Chief Executive Officer.

Business Highlights

- In May 2019, HOOKIPA achieved a second research milestone under its collaboration and license agreement with Gilead for development of a therapeutic hepatitis B virus vaccine. Based on the terms of the agreement, HOOKIPA is entitled to a milestone payment from Gilead. HOOKIPA previously completed a first research milestone for HIV in its collaboration with Gilead in December 2018.
- In April 2019, HOOKIPA completed its initial public offering (IPO), raising $84 million in gross proceeds, and commenced trading on the Nasdaq Global Select Market under the ticker symbol “HOOK”.
- In February, HOOKIPA completed a $37.4 million Series D Financing, which was led by Redmile Group with participation of additional new investors Invus and Samsara BioCapital, as well as a number of current investors.
- Michael A. Kelly, an experienced financial and biotech executive with more than 25 years of industry experience, and David R. Kaufman, currently serving as Chief Medical Officer of The Bill & Melinda Gates Medical Research Institute, were appointed to HOOKIPA’s Board of Directors.

R&D Pipeline Update
HB-101, a prophylactic vaccine for Cytomegalovirus
HB-101, HOOKIPA’s prophylactic cytomegalovirus vaccine candidate, is currently in a Phase 2 clinical trial in patients awaiting kidney transplantation from living cytomegalovirus-positive donors. HOOKIPA expects safety and immunogenicity data from the first cohorts enrolled in this trial in the first half of 2020, and preliminary efficacy data to follow in the second half of 2020.

HB-201 and HB-202, a program for the treatment of HPV - associated head and neck cancers
HOOKIPA plans to initiate a Phase 1/2 clinical trial for HB-201 in patients with treatment-refractory HPV16+ cancers in the second half of 2019. In addition, HOOKIPA also plans to combine HB-201 with a checkpoint inhibitor and to commence a Phase 1/2 trial combining HB-201 and HB-202, both with and without a checkpoint inhibitor, in patients with treatment-refractory HPV16+ cancers in the second half of 2020.

First Quarter 2019 Financial Results
HOOKIPA’s net loss for the three months ended March 31, 2019 was $9.3 million. This compares to a net loss of $4.6 million, respectively, for the same period in 2018.

Revenue was $2.2 million for the three months ended March 31, 2019, with no revenue recognized for the three months ended March 31, 2018. The increase was due to recognition of revenue under the Collaboration Agreement with Gilead, which we entered into in June 2018.

HOOKIPA’s research and development expenses for the three months ended March 31, 2019, were $10.2 million, compared to $5.0 million for the three months ended March 31, 2018. The primary driver of the increase were direct research and development expenses for the preparation of clinical trials for our HB-201 and HB-202 programs and the expansion of earlier stage projects. In addition, costs related to the Company’s collaboration with Gilead, also contributed to the increase in direct expenses.

General and administrative expenses for the three months ended March 31, 2019 and 2018 were $2.7 million and $1.5 million, respectively. The increase in general and administrative expenses was primarily due to an increase in headcount in our general and administrative functions and increase in professional and consulting fees as well as costs associated with ongoing business activities and our preparations to operate as a public company.

HOOKIPA’s cash and cash equivalents as of March 31, 2019 were $70.5 million compared to $48.6 million as of December 31, 2018. The increase was primarily attributable to $37.3 million in net proceeds received from the issuance of shares of our Series D convertible preferred stock in February 2019, offset by cash used in operating and investing activities. On April 23, 2019, HOOKIPA completed an initial public offering of its common stock by issuing 6.0 million shares of its common stock, at $14.00 per share, for gross proceeds of $84.0 million.

About HOOKIPA
HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body’s immune system.

HOOKIPA's proprietary arenavirus-based technologies, VaxWave ®*, a replication-deficient viral vector, and TheraT®*, a replication-attenuated viral vector, are designed to induce robust antigen specific CD8+ T cells and pathogen-neutralizing antibodies. Both, VaxWave® and TheraT®, are designed to allow for repeat administration while maintaining an immune response. TheraT® has the potential to induce CD8+ T cell response levels previously not achieved by other published immuno-therapy approaches. HOOKIPA's "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

HOOKIPA has completed a Phase 1 trial of a VaxWave®-based prophylactic vaccine to protect against cytomegalovirus infection and has started dosing patients in a Phase 2 trial in cytomegalovirus-negative patients awaiting kidney transplantation from cytomegalovirus-positive donors. To expand its infectious disease portfolio, HOOKIPA has entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to jointly research and develop functional cures for HIV and Hepatitis B infections. HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens.

TheraT® and VaxWave® are not approved anywhere globally and their safety and efficacy have not been established.

Find out more about HOOKIPA online at www.hookipapharma.com.

*Registered in Europe; Pending in the US.

HOOKIPA Forward Looking Statements

Certain statements set forth in this press release constitute "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements regarding (i) clinical trials (including, without limitation, the timing of filing of clinical trial applications and INDs, any approvals thereof and the timing of commencement of clinical trials) and development timelines; (ii) the number of patients that will be evaluated, the anticipated date by which enrollment will be completed and the data that will be generated by ongoing and planned clinical trials; (iii) the scope and timing of ongoing and potential future clinical trials; and (v) the sufficiency of HOOKIPA's cash resources. Such forward-looking statements involve substantial risks and uncertainties that could cause HOOKIPA's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including HOOKIPA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, HOOKIPA's ability to successfully establish, protect and defend its intellectual property and other matters that could affect the sufficiency of existing cash to fund operations. HOOKIPA undertakes no obligation to update or revise any forward-looking statements. Additional risks and uncertainties that could affect our future results are included in the section titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Prospectus dated April 17, 2019, which is available on the SEC's website at www.sec.gov and our website at www.hookipapharma.com. Additional information on potential risks will be made available in other filings that we make from time to time with the SEC.

HOOKIPA Pharma Inc.
Condensed Consolidated Statements of Operations (Unaudited)
(In thousands, except share and per share data)

	Three months ended March 31,	
	2019	**2018**
Revenue from collaboration and licensing	$ 2,235	$ —
Operating expenses:		
Research and development	(10,179)	(4,969)
General and administrative	(2,711)	(1,480)
Total operating expenses	(12,890)	(6,449)
Loss from operations	(10,655)	(6,449)
Other income (expense):		
Grant income	$ 1,192	$ 2,071
Interest income	64	—
Interest expense	(213)	(193)
Other income and expenses, net	283	22
Total other income (expense), net	1,326	1,900
Net loss before tax	(9,329)	(4,549)

Income tax expense	(0)	(24)
Net loss	$ (9,329)	$ (4,573)
Net loss per share—basic and diluted	$ (9.27)	$ (5.02)
Weighted average common shares outstanding — basic and diluted	1,006,595	911,777

For further information, please contact:

HOOKIPA
Nina Waibel
Head of Communications
Nina.Waibel@HookipaPharma.com

Media enquiries
Sue Charles/ Ashley Tapp
Instinctif Partners
Hookipa@Instinctif.com
+44 (0)20 7457 2020