HOOKIPA Pharma Reports Second Quarter 2019 Financial Results and Clinical Progress Highlights

August 12, 2019

NEW YORK and VIENNA, Austria, Aug. 12, 2019 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform, today reported recent clinical progress highlights and financial results for the second quarter ended June 30, 2019.

"In the second quarter of 2019, HOOKIPA achieved a number of major milestones, including clearance to initiate our first clinical trial in immuno-oncology and acceptance by Gilead of a set of 10 HBV viral vectors for further testing," stated Joern Aldag, HOOKIPA's Chief Executive Officer. "With the FDA's clearance of our IND application for HB-201, we are advancing our oncology program into clinical development, and are also aiming to demonstrate that our technology can effectively super-charge the natural defense mechanisms in humans and deliver prevention or cure for the benefit of seriously ill patients."

R&D Pipeline Update and Clinical Progress

HB-101, a prophylactic vaccine for cytomegalovirus
HOOKIPA's lead product candidate in infectious diseases, HB-101, is in a Phase 2 clinical trial in cytomegalovirus-negative patients awaiting kidney transplantation from living cytomegalovirus-positive donors. The majority of sites have been activated and HOOKIPA expects safety and immunogenicity data from the first cohorts enrolled in the first half of 2020, with preliminary efficacy data to follow in the second half of 2020.

HB-201 and HB-202, a program for the treatment of HPV associated cancers
In July 2019, HOOKIPA announced that its Investigational New Drug (IND) Application for a Phase 1/2 clinical trial of HB-201, a TheraT®-based immunotherapy for the treatment of Human Papilloma Virus (HPV)-positive cancers, became effective following the clearance by the U.S. Food and Drug Administration (FDA). HOOKIPA plans to initiate a Phase 1/2 clinical trial of HB-201 in patients with treatment-refractory HPV16+ cancers in the second half of 2019. This will be HOOKIPA's first clinical trial in immuno-oncology.

In addition, HOOKIPA intends to file an IND application with the FDA for HB-202 in the first half of 2020, 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 late 2020.

Strategic collaborations

Progress under Gilead collaboration for therapeutic hepatitis B virus (HBV) and human immunodeficiency virus (HIV)
In May 2019, HOOKIPA achieved a $2m research milestone for HBV by designing and delivering 10 research-grade vectors to Gilead Sciences, Inc., or Gilead, along with the characterization of these vectors and delivery of a data package for the HBV program. These research vectors will be subject to further pre-clinical testing in order to validate a clinical candidate for novel combination therapies for the treatment of HBV. This follows the delivery of 14 research-grade vectors for the HIV program in January 2019.

Board and management

David Kaufman joined HOOKIPA's Board of Directors
In April 2019, HOOKIPA announced the appointment of David R. Kaufman, M.D., Ph.D., to its Board of Directors. Dr. Kaufman currently serves as Chief Medical Officer of The Bill & Melinda Gates Medical Research Institute. Dr. Kaufman's expertise as an immunologist and in oncology research and development are expected to be a tremendous addition to help maximize the potential of HOOKIPA's proprietary arenavirus platform to target infectious diseases and cancers.

Second Quarter 2019 Financial Results

HOOKIPA's net loss for the three months ended June 30, 2019 was $12.1 million, compared to a net loss of $5.8 million for the three months ended June 30, 2018.

Revenue was $4.1 million for the three months ended June 30, 2019, compared to $0.6 million for the three months ended June 30, 2018. The increase was due to recognition of revenue under the Collaboration Agreement with Gilead.

HOOKIPA's research and development expenses for the three months ended June 30, 2019, were $13.9 million, compared to $6.2 million for the three months ended June 30, 2018. The primary driver of the increase was an increase in direct research and development expenses of $6.4 million. Direct research and development expenses increased primarily due to the preparation costs of clinical trials for HOOKIPA's HB-201 and HB-202 programs and the expansion of earlier stage programs. In addition, costs related to HOOKIPA's collaboration with Gilead contributed to the increase in direct expenses. Internal research and development expenses increased by $1.3 million, primarily as a result of increased research and development headcount.

General and administrative expenses for the three months ended June 30, 2019 were $3.8 million, compared to $1.4 million for the three months ended June 30, 2018. The increase was mainly due to the growth in headcount in HOOKIPA's general and administrative functions and an increase in professional and consulting fees as well as costs associated with ongoing business activities and costs to operate as a public company.

HOOKIPA's cash and cash equivalents as of June 30, 2019 were $135.2 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 Series D convertible preferred stock in February 2019, and $74.6 million in net proceeds received from HOOKIPA's initial public offering in April 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.

Upcoming Investor Events

- Wells Fargo 2019 Healthcare Conference, September 4 - 5, 2019
- BioCentury Conference NewsMakers in the Biotech Industry, September 6, 2019
- Bank of America Merrill Lynch Global Healthcare Conference, September 18-20, 2019

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 technologies 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's VaxWave ®-based prophylactic cytomegalovirus vaccine candidate is currently in a Phase 2 clinical trial in patients awaiting kidney transplantation from living 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. Forward-looking statements can be identified by terms such as "believes," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms. 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 and HOOKIPA's ability to achieve the milestones under the agreement with Gilead. HOOKIPA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see HOOKIPA's quarterly report on Form 10-Q for the quarter ended March 31, 2019 which is available on the Security and Exchange Commission's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com.

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

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Revenue from collaboration and licensing	$ 4,051	$ 649	$ 6,286	$ 649
Operating expenses:				
Research and development	(13,929)	(6,211)	(24,108)	(11,180)
General and administrative	(3,751)	(1,413)	(6,462)	(2,893)
Total operating expenses	(17,680)	(7,624)	(30,570)	(14,073)
Loss from operations	(13,629)	(6,975)	(24,284)	(13,424)
Other income (expense):				
Grant income	1,544	1,384	2,736	3,455
Interest income	511	0	575	0
Interest expense	(210)	(191)	(423)	(384)
Other income and expenses, net	(195)	(36)	88	(14)
Total other income (expense), net	1,650	1,157	2,976	3,057
Net loss before tax	(11,979)	(5,818)	(21,308)	(10,367)
Income tax expense	(100)	(1)	(100)	(25)

Net loss	$ (12,079)	$ (5,819)	$ (21,408)	$ (10,392)

	As of June 30, 2019	As of December 31, 2018
Cash, cash equivalents and restricted cash	$ 135,213	$ 48,580
Total assets	168,095	68,251
Total liabilities	32,062	23,852
Redeemable convertible preferred stock	-	104,774
Total stockholders' equity	136,033	(60,375)

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