HOOKIPA Pharma Reports Third Quarter 2020 Financial Results and Provides a Corporate Update

November 12, 2020

NEW YORK and VIENNA, Austria, Nov. 12, 2020 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today reports its financial results for the third quarter ended September 30, 2020 and provides a corporate update.

"The third quarter saw continued advancement and validation of our clinical development programs, with a focus on our oncology pipeline of replicating arenavirus-based therapeutic candidates," commented Joern Aldag, Chief Executive Officer of HOOKIPA. "We continue to gain momentum as we expanded our ongoing Phase 1/2 HPV trial to explore HB-202/HB-201 as an alternating vector therapy with the first patient dosed with HB-202. We are also pleased that preclinical immunogenicity data from HB-201, our lead oncology candidate, was recognized in *OncoImmunology*, further demonstrating the potential of our arenavirus-based therapies to combat cancer. Additionally, I am proud that Professor Jean-Charles Soria, a globally recognized scientist and oncologist, who is General Director of Gustave Roussy, the leading European Cancer Center, joined our Board of Directors. His expertise will enhance our efforts as we seek to advance new, much needed cancer therapies."

R&D Pipeline Update and Clinical Progress

HB-101, lead product candidate in infectious diseases
HOOKIPA's prophylactic Cytomegalovirus (CMV) vaccine candidate, HB -101, is in a randomized, double-blinded Phase 2 clinical trial in patients awaiting kidney transplantation who are at risk for CMV-associated complications post-transplant. In June 2020, HOOKIPA announced positive Phase 2 interim data on the trial's primary endpoints: safety, and B cell and T cell immunogenicity. The interim data demonstrated that HB -101 was well tolerated, with a lower rate of adverse events in patients with end-stage kidney disease than in the Phase 1 healthy volunteer trial. Patients who received the sponsor recommended three doses of HB-101 showed comparable immunogenicity levels to those measured in the Phase 1 healthy volunteer trial. HOOKIPA continues to accrue patients and plans to report preliminary efficacy and updated safety and immunogenicity data by the end of 2020.

HB-201 and HB-202, lead programs in immuno-oncology treating Human Papillomavirus-positive cancers
HOOKIPA's lead oncology product candidates, HB -201 and HB-202, are in development for the treatment of Human Papillomavirus 16-positive (HPV16+) cancers. In December 2019, HOOKIPA initiated the Phase 1/2 clinical trial with endpoints of safety, immunogenicity and efficacy. The open label, dose escalating Phase 1/2 clinical trial in HPV16+ cancers is currently evaluating HB-201 alone and subsequently in combination with an approved checkpoint inhibitor. Accrual of patients for the first and the second dose levels at a three-week dosing frequency has been completed without safety concerns. Additional dose schedules and levels are being investigated to identify the recommended Phase 2 dose. HOOKIPA expects to report preliminary safety and efficacy data in late 2020 or early 2021.

A peer reviewed article in *OncoImmunology* issued in September 2020 recognized that HB-201 preclinical results demonstrated high immunogenicity. The paper verified that systemically administered HB-201 leads to dose-dependent induction of a robust, systemic cytotoxic T cell response directed against HPV16 proteins, tumor infiltration of HPV16 specific cytotoxic T cells, as well as significantly delayed tumor growth or complete tumor clearance accompanied with prolonged survival.

In October 2020, HOOKIPA announced the dosing of the first patient with HB-202. HB-202 is part of a sequential alternating vector regimen of HB-202/HB-201 for the treatment of $HPV16^{+}$ cancers in the ongoing HB-201 Phase 1/2 trial. In pre-clinical studies, alternating administration of HB-202 and HB-201 resulted in a ten-fold increase in immune response and better disease control than either compound alone. The Company expects to provide interim safety, dose escalation, and efficacy data on the HB-202/HB-201 arm of the ongoing Phase 1/2 study in mid-2021.

Strategic Collaborations

Gilead Sciences Collaboration for HIV and HBV Therapeutic Vaccines
Since the start of the collaboration in 2018, HOOKIPA has received $21.0 million in upfront and milestone payments from Gilead for the delivery of research vectors and for advancing the programs towards clinical trials, including a milestone payment of $4.0 million, which the Company received in early 2020. Based on preclinical data generated to date, Gilead committed to advancing the HBV and HIV vectors toward development. To enable the development activities and expanded research programs, Gilead agreed to reserve manufacturing capacity and increase reimbursement planned for the Company's expanded resources allocated to the Gilead collaboration.

Others
In October 2020, Professor Jean-Charles Soria, M.D., Ph.D., was appointed to HOOKIPA's Board of Directors. Jean-Charles Soria is Professor of Medicine and Medical Oncology at the University of Paris-Saclay and currently serves as General Director of the Gustave Roussy Cancer Center, one of the world's leading cancer research institutes.

COVID-19
HOOKIPA continues to monitor the COVID-19 pandemic closely and adapt to COVID-19 measures and recommendations issued by the U.S. and Austrian governments. For disclosures of risks and uncertainties resulting from the COVID-19 disease outbreak, including the impact on the enrollment of patients and timing of clinical results, see HOOKIPA's quarterly reports on Form 10-Q for the quarters ended June 30, 2020 and September 30, 2020.

Third Quarter 2020 Financial Results

Cash Position:

HOOKIPA's cash, cash equivalents and restricted cash as of September 30, 2020 was $82.3 million compared to $113.6 million as of December 31, 2019. The decrease was primarily attributable to cash used in operating activities.

Revenue was $4.0 million for the three months ended September 30, 2020 compared to $2.0 million for the three months ended September 30, 2019. The increase was primarily due to higher cost reimbursements received under the collaboration agreement with Gilead following the expansion of the collaboration in the first half of 2020 and the partial recognition of a milestone payment we received from Gilead in February 2020.

Research and Development Expenses:
HOOKIPA's research and development expenses were $16.0 million for the three months ended September 30, 2020 compared to $11.0 million for the three months ended September 30, 2019. The primary drivers of the increase compared to 2019 were an increase in clinical trial expenses of $2.7 million and an increase in internal research and development expenses of $2.3 million.

General and Administrative Expenses:

General and administrative expenses amounted to $4.4 million for the three months ended September 30, 2020 compared to $4.6 million for the three months ended September 30, 2019. The decrease was primarily due to a decrease in personnel-related expenses of $0.1 million, a decrease in professional and consulting fees of $0.5 million, partially offset by an increase of other general and administrative expenses of $0.4 million.

Net Loss:

HOOKIPA's net loss was $13.6 million for the three months ended September 30, 2020 compared to a net loss of $11.4 million for the three months ended September 30, 2019.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics based on its proprietary arenavirus platform that reprograms the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, non-replicating (VaxWave ®) and replicating (TheraT®), induce robust antigen-specific $CD8^+$ T cells and pathogen-neutralizing antibodies. HOOKIPA's viral vectors target antigen presenting cells in vivo to activate the immune system. Both technologies enable repeat administration to augment and refresh immune responses. As a monotherapy, our replicating arenavirus technology has the potential to induce $CD8^+$ T cell response levels previously not achieved by other immuno-therapy approaches.

HOOKIPA's non-replicating prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial for patients awaiting kidney transplantation. To expand its infectious disease portfolio, HOOKIPA entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to research arenavirus-based functional cures for HIV and chronic Hepatitis B infections.

In addition, HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens. The lead replicating arenavirus oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papilloma Virus 16-positive cancers in a Phase 1/2 clinical trial.

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

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, risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises, the impact of COVID-19 on the enrollment of patients and timing of clinical results for HB-101 and other programs, 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 September 30, 2020 which is available on the Security and Exchange Commission's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com.

Investors and others should note that we announce material financial information to our investors using our investor relations website (https://ir.hookipapharma.com/), SEC filings, press releases, public conference calls and webcasts. We use these channels, as well as social media, to communicate with our members and the public about our company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the U.S. social media channels listed on our investor relations website.

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenue from collaboration and licensing	$ 4,040	$ 2,038	$ 14,421	$ 8,324

Operating expenses:				
Research and development	(16,009)	(11,025)	(39,099)	(35,133)
General and administrative	(4,437)	(4,589)	(13,413)	(11,051)
Total operating expenses	(20,446)	(15,614)	(52,512)	(46,184)
Loss from operations	(16,406)	(13,576)	(38,091)	(37,860)
Total interest, other income and taxes, net	2,817	2,191	6,483	5,067
Net loss	$ (13,589)	$ (11,385)	$ (31,608)	$ (32,793)
Net loss per share — basic and diluted	(0.53)	(0.45)	(1.23)	(2.14)
Weighted average common shares outstanding — basic and diluted	25,659,504	25,408,488	25,645,827	15,308,071

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of September 30, 2020	As of December 31, 2019
Cash, cash equivalents and restricted cash	$ 82,259	$ 113,575
Total assets	121,272	143,745
Total liabilities	29,092	25,846
Total stockholders' equity	92,180	117,899

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