HOOKIPA Reports Fourth Quarter and Full Year 2020 Financial Results and Provides 2021 Outlook

March 18, 2021

- Proprietary arenavirus immunotherapeutics platform demonstrated promising clinical activity with interim data from lead oncology and infectious disease candidates
- Follow-on offering strengthened cash basis with $143 million available at year-end to support progression of Human Papillomavirus 16-positive (HPV16+) cancer and Cytomegalovirus (CMV) programs and pipeline expansion
- HOOKIPA on track to report additional clinical data on efficacy and T cell response in 2021 for HB-201 and HB-202

NEW YORK and VIENNA, Austria, March 18, 2021 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, "HOOKIPA"), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today reported financial results and provided a corporate update for the fourth quarter and full year 2020.

"Despite the global pandemic, 2020 was a break-out year for HOOKIPA, a testament to the strength of our novel scientific platform and our dedicated team. We reported compelling, early clinical data with both our replicating and non-replicating technologies in oncology and infectious diseases, respectively, and advanced the HBV and HIV cures towards the clinic in our strategic collaboration with Gilead Sciences. With the appointment of Jean-Charles Soria, M.D., Ph.D., we added a globally recognized oncology expert to our board to help guide our clinical development progress," said Joern Aldag, Chief Executive Officer at HOOKIPA. "Our strong year-end cash balance of $143 million positions us well to advance our CMV and HPV16+ cancer programs and to expand our pipeline. Given the strength of the interim data reported in 2020, we are excited about the further potential of our platform and additional read-outs this year, particularly from our HB-201/HB-202 two-vector alternating immunotherapy, which has the potential to deliver even greater immune response than HB-201 alone."

R&D Pipeline Update and Clinical Progress

Oncology Portfolio (HB-201 and HB-202)

- **Clinical proof of concept achieved with HB-201.** In December, interim Phase 1 data on HB-201 for the treatment of advanced HPV16+ cancers showed promising anti-tumor activity and favorable tolerability as a monotherapy, i.e. without any additional combination product. Data demonstrated responses and stable disease in head and neck cancer patients who failed prior standard of care therapy, platinum therapy, PD(L)1 inhibitor, or both. By targeting an antigen common to HPV16+, HB-201 has the potential to be a tumor-agnostic therapy for all HPV16+ cancers. These early-stage data establish proof of concept for HOOKIPA's replicating single-vector immunotherapy in oncology. Dose escalation and dose frequency continue to be evaluated in the ongoing Phase 1/2 trial, with the next data read-out anticipated by mid-2021. HPV is estimated to cause 5% of the worldwide cancer burden, the majority of which is HPV16+.
- **First patient dosed with HB-202.** HOOKIPA expanded its Phase 1/2 HB-201 clinical trial to include evaluation of HB-201/HB-202, an alternating two-vector therapy. Following clearance of the IND by the Food and Drug Administration in June 2020, the first patient was dosed with HB-202 in October 2020. Preclinical data show that adding an additional arenaviral vector to achieve alternating two-vector therapy can enhance the immune response. Initial data read-out is anticipated by mid-2021.
- ***OncoImmunology* published HB-201 pre-clinical data demonstrating high immunogenicity.** In September, pre-clinical data on HB-201 in HPV16+ models were published in *OncoImmunology.* Specifically, intravenous administration of HB-201 elicited a robust expansion of antigen-specific CD8+ T cell responses. In the HPV16+ tumor model, HB-201 showed significantly delayed tumor growth or complete tumor clearance with prolonged survival.
- **Pre-clinical data highlighting the potential of alternating two-vector cancer therapeutics published in *Cell Reports Medicine*.** The March 2021 issue of *Cell Reports Medicine* featured pre-clinical data showing that alternating, intravenous administration of two replicating arenaviral vectors induced tumor-specific responses exceeding 50% of circulating CD8 T cells. In addition, the two-vector approach resulted in tumor cures and long-term immunity in a pre-clinical setting. HOOKIPA is currently evaluating the alternating two-vector therapy in its ongoing HB-201/HB-202 clinical trial, with initial data read-out anticipated by mid-2021.

Infectious Disease Portfolio (HB-101)

- **Clinical proof of concept achieved with HB-101.** In November, interim Phase 2 data were released for patients who received a three-dose CMV vaccination with HB-101 prior to a kidney organ transplantation. These interim results showed a reduction in CMV viremia, reduction in antiviral use, and no CMV disease in the CMV-negative kidney transplant recipients as compared to placebo. Strong CMV-neutralizing antibody responses and a favorable tolerability profile were

also observed. HOOKIPA believes that these interim data establish proof of concept for HB-101, a potential first-in-class vaccine candidate, which uses HOOKIPA's non-replicating technology. HOOKIPA expects to conclude enrollment of the ongoing Phase 2 trial in mid-2021 and to report additional data in the second half of 2021.

- **Scientific validation with Phase 1 HB-101 data publication in *The Journal of Infectious Diseases.*** In April, Phase 1 safety and immunogenicity data on HB-101 were published in *The Journal of Infectious Diseases.* The trial concluded that the CMV vaccine candidate was well-tolerated and induced strong neutralizing antibody and T cell immune responses against CMV in healthy adult volunteers.

Strategic Collaborations

- **Gilead Sciences collaboration for Hepatitis B Virus and HIV therapeutic vaccines advances.** HOOKIPA's collaboration with Gilead aims to develop immunotherapy candidates for functional cures of Hepatitis B Virus and HIV in combination therapies. Significant progress was made in the collaboration during 2020. In the fourth quarter, another pre-clinical milestone was triggered in the HIV program, bringing the total revenue recorded from the Gilead collaboration in 2020 to $19.6 million. Gilead agreed to reserve manufacturing capacity and expanded resources to support future clinical trials.

Corporate Highlights

- **Balance sheet strengthened with $80.9m financing.** Following the positive data read-outs in both the oncology and infectious disease programs, HOOKIPA completed a successful follow-on offering to close the year with a cash balance of $143.2 million. Funding will support advancement of the HPV16+ and CMV programs and an expansion of the overall pipeline.
- **Board of Directors adds expertise in late-stage oncology clinical development.** In October, HOOKIPA welcomed Professor Jean-Charles Soria, M.D., Ph.D., Director General of the Gustave Roussy Cancer Center in Paris, as a Board Director. Dr. Soria is a globally recognized physician-scientist who brings deep oncology, immunotherapy and clinical development expertise to the Board.
- **Strong management through COVID-19 uncertainty.** Despite the challenges of the pandemic, HOOKIPA's team was able to continue to deliver effectively on our corporate goals. HOOKIPA quickly pivoted early on to maintain its laboratory and manufacturing operations with appropriate safety precautions, while other employees were able to maintain productivity via remote work. HOOKIPA continues to monitor the impact of the ongoing pandemic on its overall operations.

Upcoming Milestones

- Translational data from the HB-201 program in Q2 2021
- Additional HB-201 and initial HB-201/HB-202 Phase 1/2 efficacy data in HPV16+ cancers in mid-2021
- Additional HB-101 CMV Phase 2 efficacy data in H2 2021
- Advancing HB-300 towards IND for the treatment of metastatic prostate cancer
- HBV and HIV collaboration with Gilead Sciences advancing towards clinical studies

Fourth Quarter and Full Year 2020 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of December 31, 2020 was $143.2 million compared to $113.6 million as of December 31, 2019. The increase was primarily attributable to $75.0 million in net proceeds from the issuance of common stock and convertible preferred stock in a follow-on financing in December 2020, offset by cash used in operating activities.

Revenue was $5.2 million for the three months ended December 31, 2020, and $19.6 million for the year ended December 31, 2020 compared to $3.6 million for the three months ended December 31, 2019 and $11.9 million for the year ended December 31, 2019. The increase was primarily due to higher cost reimbursements received under the collaboration agreement with Gilead 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 $15.7 million for the three months ended December 31, 2020, and $54.8 million for the year ended December 31, 2020 compared to $11.2 million for the three months ended December 31, 2019, and $46.3 million for the year ended December 31, 2019.

The primary driver of the increase in research and development expenses by $8.5 million compared to 2019 was an increase in internal research and development expenses, partially offset by a decrease in direct research and development expenses.

Internal research and development expenses increased primarily due to higher personnel expenses, including stock based compensation and an increase in facility related expenses. The decrease in direct expenses was primarily due to a decrease in research and development service expenses, along with a decrease in manufacturing and quality control expenses and a decrease of other direct research and development expenses, partially offset by an increase in clinical trial expenses and an increase in laboratory expenses.

General and Administrative Expenses: General and administrative expenses amounted to $4.7 million for the three months ended December 31, 2020 and $18.1 million for the for the year ended December 31, 2020 compared to $5.7 million for the three months ended December 31, 2019, and $16.7 million for the year ended December 31, 2019. The increase was mainly due to the growth in personnel related expenses as well as costs associated with ongoing business activities and costs to operate as a public company, partially offset by a decrease in professional and consulting fees.

Net Loss: HOOKIPA's net loss was $12.5 million for the three months ended December 31, 2020 and $44.1 million for the year ended December 31, 2020 compared to a net loss of $10.2 million for the three months ended December 31, 2019 and $43.0 million for the year ended December 31, 2019. This increase was due to an increase in research and development expenses, mainly driven by the progression of HOOKIPA's oncology programs, and an increase in general and administrative expenses to operate as a public company.

Conference call: HOOKIPA will host a conference call and live webcast at 8:30 am EDT to discuss its financial results. Please register here to access the conference call. The webcast and the presentation will be available within the Investors & Media section of HOOKIPA's website at https://ir.hookipapharma.com/events. An archived replay will be accessible for 30 days following the event.

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 and replicating, 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 not used in combination, our replicating arenavirus technology has the potential to induce CD8+ T cell response levels previously not achieved by other immuno-therapy approaches.

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.

HOOKIPA's non-replicating prophylactic Cytomegalovirus vaccine candidate, HB-101, 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.

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-K for the quarter ended December 31, 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 December 31,		Year ended December 31,	
	2020	2019	2020	2019
Revenue from collaboration and licensing	$ 5,163	$ 3,618	$ 19,584	$ 11,942
Operating expenses:				
Research and development	(15,688)	(11,179)	(54,787)	(46,312)
General and administrative	(4,669)	(5,664)	(18,082)	(16,715)
Total operating expenses	(20,357)	(16,843)	(72,869)	(63,027)
Loss from operations	(15,194)	(13,225)	(53,285)	(51,085)
Total interest, other income and taxes, net	2,719	2,981	9,203	8,048
Net loss	$ (12,475)	$ (10,244)	$ (44,082)	$ (43,037)
Net loss per share — basic and diluted	(0.46)	(0.40)	(1.69)	(2.41)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of December 31, 2020	As of December 31, 2019
Cash, cash equivalents and restricted cash	$ 143,177	$ 113,575
Total assets	187,817	143,745
Total liabilities	31,694	25,846
Total stockholders' equity	156,123	117,899

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