HOOKIPA Pharma Reports Third Quarter 2023 Financial Results and Recent Business Highlights

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- Reported positive preliminary Phase 2 data on additional patients for HB-200 in combination with pembrolizumab in the 1st-line setting for advanced HPV16+ head and neck cancer; data reinforce strong objective response rate and disease control rate reported in Q2 2023; randomized trial expected to start in 2024
- Published peer-reviewed preclinical data, in collaboration with Gilead Sciences, for HB-400 program in *The Journal of Infectious Disease*
- Recruitment ongoing for two Phase 1 clinical trials (HB-300 for advanced prostate cancer and Gilead-partnered HB-400 for chronic hepatitis B)
- IND-enabling activities in progress to advance two additional therapeutic candidates into the clinic in 2024 (Gilead-partnered HB-500 for HIV and Roche-partnered HB-700 for KRAS-mutated cancers)

NEW YORK and VIENNA, Austria, Nov. 09, 2023 (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 business highlights for the third quarter of 2023.

"I am pleased by the consistent and strong data within our HB-200 program; not only is our mechanism delivering powerful antigen-specific T cell responses, but it has also helped our patients continue their fight against cancer with promising objective response rate and disease control rate. With these encouraging data, we are busy finalizing plans for the randomized trial expected to begin next year," said Joern Aldag, Chief Executive Officer at HOOKIPA Pharma. "We also have significant, and achievable, upcoming milestones across our portfolio of programs, a testament to the potential of arenaviral platform technology to address unmet needs in cancer and infectious diseases."

Business Highlights and Recent Developments

Oncology

- In October, HOOKIPA announced positive preliminary Phase 2 data on additional patients for HB-200 in combination with pembrolizumab, in patients with recurrent/metastatic Human Papillomavirus 16-positive (HPV16+) head and neck cancers, which was consistent with the preliminary data HOOKIPA announced in May 2023. Data from the ongoing study (NCT04180215), which was presented at the European Society for Medical Oncology Congress 2023, showed a 42 percent objective response rate for 19 evaluable checkpoint inhibitor (CPI)-naïve patients treated with HB-200 in combination with pembrolizumab. These data represent a doubling of the historical response rate (19 percent) reported for pembrolizumab alone and are consistent with previously reported data from the Phase 2 trial. HOOKIPA is preparing to start a randomized trial of HB-200 in combination with pembrolizumab in the 1st-line setting for patients with recurrent/metastatic HPV16+ head and neck cancers in mid-2024.
- Enrollment continued in the ongoing Phase 1/2 study (NCT05553639) of HB-300 for the treatment of advanced prostate cancer. HB-300 is an arenaviral immunotherapy that targets two well-defined self-antigens of prostate cancer, prostatic acid phosphatase (PAP) and prostate-specific antigen (PSA). Initial safety, tolerability and immunogenicity data from the ongoing Phase 1 study of HB-300 are expected in the first half of 2024.
- HOOKIPA's HB-700 program, in collaboration with Roche, is progressing to an expected Investigational New Drug (IND) application filing in the first half of 2024. HB-700 is a novel arenaviral immunotherapy for KRAS-mutated cancers, including the five mutations that are the primary causes of lung, pancreatic and colon cancers.

Infectious disease

- In August, *The Journal of Infectious Disease,* published peer-reviewed preclinical data on HB-400, an investigational therapeutic vaccine for chronic hepatitis B (HBV). The data show that HB-400 (NCT05770895) induced robust, HBV-specific T cell and antibody responses in non-human primates and cleared detectable serum HBV antigens in a mouse model for chronic HBV infection, with near elimination of detectable HBV antigen positive hepatocytes in the liver. HB-400 currently being evaluated in a Phase 1 trial and is one of two independent development programs in HOOKIPA's collaboration and license agreement with Gilead Sciences, Inc. Gilead is solely responsible for further development and commercialization of the HBV product candidate.

- HOOKIPA's HB-500 program, also partnered with Gilead, is progressing towards an anticipated IND filing in the fourth quarter of 2023 and is expected to commence a Phase 1 clinical trial in 2024. HB-500 is a novel arenaviral vaccine that will be assessed as part of a potential functional curative regimen for HIV.

Anticipated Milestones

- Phase 2 HB-200 in HPV16+ head and neck cancers
  - 1st-line follow-up data in combination with pembrolizumab: H1 2024
  - Start of 1st-line randomized study in combination with pembrolizumab: mid-2024 (Fast Track designation)
- Phase 1 HB-300 in prostate cancer
  - Preliminary safety and immunogenicity data: H1 2024
- HB-700 in KRAS-mutated cancers: IND filing H1 2024
- HB-400 in hepatitis B: to be determined by Gilead
- HB-500 in HIV: IND filing Q4 2023

Third Quarter 2023 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of September 30, 2023 was $108.1 million compared to $113.4 million as of December 31, 2022. The decrease was primarily attributable to cash used in operating activities, partly offset by funds resulting from the follow-on financing in June 2023.

Revenue: Revenue was $6.9 million for the three months ended September 30, 2023 and $2.2 million for the three months ended September 30, 2022. This increase was primarily due to higher partial recognition of the upfront and milestone payments under the Gilead and Roche collaborations, cost reimbursements for activities related to the preparation of a first human trial under the Roche collaboration, partially offset by lower cost reimbursements received under the Restated Gilead Collaboration Agreement.

Research and Development Expenses: HOOKIPA's research and development expenses were $24.6 million for the three months ended September 30, 2023, compared to $18.3 million for the three months ended September 30, 2022. The primary drivers of the increase in research and development expenses by $6.3 million were higher clinical study expenses for our HB-200 program and increased spending for our Roche partnered program.

General and Administrative Expenses: General and administrative expenses amounted to $4.9 million for the three months ended September 30, 2023 and the three months ended September 30, 2022, respectively. General and administrative expenses remained constant.

Net Loss: HOOKIPA's net loss was $19.1 million for the three months ended September 30, 2023, compared to a net loss of $18.3 million for the three months ended September 30, 2022. This increase was primarily due to an increase in research and development expenses.

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,	
	2023	2022	2023	2022
Revenue from collaboration and licensing	$ 6,867	$ 2,230	$ 12,722	$ 6,421
Operating expenses:				
Research and development	(24,625)	(18,286)	(65,262)	(51,053)
General and administrative	(4,912)	(4,937)	(14,259)	(14,935)
Total operating expenses	(29,537)	(23,223)	(79,521)	(65,988)
Loss from operations	(22,670)	(20,993)	(66,799)	(59,567)
Total interest, other income and taxes, net	3,604	2,713	10,037	6,963
Net loss	$ (19,066)	$ (18,280)	$ (56,762)	$ (52,604)
Net loss per share — basic and diluted	(0.17)	(0.25)	(0.64)	(0.83)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of September 30, 2023	As of December 31, 2022
Cash, cash equivalents and restricted cash	$ 108,095	$ 113,444
Total assets	164,010	170,454
Total liabilities	68,959	67,937

Total stockholders' equity	95,051	102,517

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies, based on its proprietary arenavirus platform, which are designed to mobilize and amplify targeted T cells and thereby fight or prevent serious disease. HOOKIPA's replicating and non-replicating technologies are engineered to induce robust and durable antigen-specific CD8+ T cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly owned investigational arenaviral immunotherapies targeting Human Papillomavirus 16-positive cancers, prostate cancers, and other undisclosed programs. HOOKIPA is collaborating with Roche on an arenaviral immunotherapeutic for KRAS-mutated cancers. In addition, HOOKIPA aims to develop functional cures of HBV and HIV in collaboration with Gilead.

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

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 "anticipates", "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, plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, the ability to initiate new clinical programs, the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical and clinical trials, including those for HB-200, HB-300 HB-400, HB-700 and HB500, 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 public health crises, the impact of public health crises on the enrollment of patients and timing of clinical results, 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. 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 Annual Report on Form 10-K for the year ended December 31, 2022 and most recent quarterly report on Form 10-Q, and as well as discussions of potential risks, uncertainties, and other important factors in HOOKIPA's subsequent filings with the Securities and Exchange Commission, which are available on the SEC's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com. All information in this press release is as of the date of the release, and HOOKIPA undertakes no duty to update this information unless required by law.

Availability of Other Information About HOOKIPA

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.

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