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

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- HOOKIPA reported positive preliminary Phase 2 data on HB-200 in combination with pembrolizumab in 1st-line setting for advanced head and neck cancer
- 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 therapeutics into the clinic in 2024 (Gilead-partnered HB-500 for HIV and Roche-partnered HB-700 for KRAS-mutated cancers)
- $50 million follow-on offering strengthened cash basis to support initiation of randomized study of HB-200 in combination with pembrolizumab in H1 2024

NEW YORK and VIENNA, Austria, Aug. 10, 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 second quarter of 2023.

"A key highlight was reporting our positive preliminary Phase 2 data on HB-200 in combination with pembrolizumab for advanced head and neck cancer. We continue to collect evidence that our novel arenaviral technology may help address unmet needs in cancer, with greater objective response rates than the current standard of care and clear trends towards duration of clinical benefit," said Joern Aldag, Chief Executive Officer at HOOKIPA Pharma. "We're pleased investors also acknowledged the strength of our data with the $50 million capital raise. We're now focused on preparing for the randomized trial of HB-200 in combination with pembrolizumab to start in the first half of 2024, as well as continuing to advance our clinical programs and diverse pipeline overall."

Quarter highlights

Oncology

- In May, HOOKIPA announced positive preliminary Phase 2 data on HB-200 in combination with pembrolizumab in patients with recurrent/metastatic Human Papillomavirus 16-positive (HPV16+) head and neck cancers. Data from the ongoing study (NCT04180215) showed a 43 percent objective response rate with HB-200 in combination with pembrolizumab in checkpoint inhibitor (CPI)-naïve patients, doubling the response rate for pembrolizumab alone. HOOKIPA plans to share more data at a medical conference later this year and is preparing to start a randomized trial of HB-200 with pembrolizumab in the 1st-line setting in 2024.

- In June, HOOKIPA presented a trial-in-progress presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on its 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). The ability to break immune tolerance and mount a strong T cell response against these self-antigens remains an unmet need in prostate cancer. Preclinical studies have demonstrated the ability of HOOKIPA's arenaviral technology to break tolerance and elicit a strong immune response against self-antigens. 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 lung, pancreatic and colon cancers.

Infectious disease

- In May, HOOKIPA announced that the first participant had been dosed in a Gilead's Phase 1 clinical trial (NCT05770895) of HB-400, an investigational therapeutic vaccine for chronic hepatitis B using HOOKIPA's arenaviral platform. HB-400 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 hepatitis B product candidate.

- HOOKIPA's HB-500 program, partnered with Gilead, is progressing towards an anticipated IND filing in the second half 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.

Corporate

- In June, HOOKIPA completed a $50 million public offering of common stock and non-voting convertible preferred stock. The net proceeds will support the randomized study of HB-200 in combination with pembrolizumab, as well as other clinical programs.

- In August, the board of directors approved an exchange offer to eligible employees, excluding executive officers, members of the board of directors and members of HOOKIPA's scientific advisory board, for certain underwater stock options. A total of 627,632 options with an exercise price per share greater than $6.50 will be eligible for exchange into up to a total of 315,505 new stock options with modified terms and an exercise price per share equal to the closing price on the grant date of the new option, but not less than $1.00. The exchange offer shall be made pursuant and subject to a tender offer statement, including an offer to exchange, to be filed with the Securities and Exchange Commission (SEC) today, which shall be the only basis for such offer.

Upcoming Milestones

- Phase 2 HB-200 in HPV16+ head and neck cancers
  - 1st-line follow-up data in combination with pembrolizumab: H1 2024
  - 2nd+-line follow-up data in combination with pembrolizumab: Q1 2024
  - Start of 1st-line randomized study in combination with pembrolizumab: H1 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 2023

Second Quarter 2023 Financial Results
Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of June 30, 2023 was $136.0 million compared to $113.4 million as of December 31, 2022. The increase was primarily attributable to funds resulting from the follow-on financing in June 2023, partly offset by cash used in operating activities.

Revenue: Revenue was $2.7 million for the three months ended June 30, 2023 and for the three months ended June 30, 2022. A decrease of cost reimbursements received under the Restated Gilead Collaboration Agreement, was largely offset by higher partial recognition of the upfront and milestone payments under the Gilead collaboration and Roche collaboration.

Research and Development Expenses: HOOKIPA's research and development expenses were $19.7 million for the three months ended June 30, 2023, compared to $16.1 million for the three months ended June 30, 2022. The primary drivers of the increase in research and development expenses by $3.6 million compared to the three months ended June 30, 2022 were higher clinical study expenses for our HB-200 and HB-300 programs as well as increased spending for our Gilead and Roche partnered programs.

General and Administrative Expenses: General and administrative expenses amounted to $4.4 million for the three months ended June 30, 2023, compared to $5.0 million for the three months ended June 30, 2022. The decrease was primarily due to a decrease in other expenses, and a decrease in personnel-related expenses, partially offset by an increase in professional and consulting fees. The decrease in personnel-related expenses resulted from decreased stock compensation expenses, partially offset by a growth in headcount along with increased salaries in our general and administrative functions as well as expenses for contractors.

Net Loss: HOOKIPA's net loss was $18.0 million for the three months ended June 30, 2023, compared to a net loss of $16.4 million for the three months ended June 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenue from collaboration and licensing	$ 2,679	$ 2,746	$ 5,855	$ 4,191
Operating expenses:				
Research and development	(19,706)	(16,147)	(40,637)	(32,767)
General and administrative	(4,445)	(5,026)	(9,347)	(9,998)
Total operating expenses	(24,151)	(21,173)	(49,984)	(42,765)

Loss from operations	(21,472)	(18,427)	(44,129)	(38,574)
Total interest, other income and taxes, net	3,456	2,071	6,433	4,250
Net loss	$ (18,016)	$ (16,356)	$ (37,696)	$ (34,324)
Net loss per share — basic and diluted	(0.22)	(0.23)	(0.49)	(0.58)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of June 30, 2023	As of December 31, 2022
Cash, cash equivalents and restricted cash	$ 136,009	$ 113,444
Total assets	191,110	170,454
Total liabilities	78,780	67,937
Total stockholders' equity	112,330	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.

Important Note Regarding the Stock Option Exchange

The description of the stock option exchange contained in this release is provided for informational purposes only and is neither an offer to exchange nor a solicitation of an offer to exchange any of the Company's securities. The offer to exchange and the solicitation of securities eligible to be exchanged will be made only pursuant to an offer to exchange and other related materials which will be disseminated to eligible persons and filed with the SEC later today pursuant to a Tender Offer Statement on Schedule TO (the "Tender Offer Statement"). Option holders should read those materials and the documents referenced therein carefully when they become available because they will contain important information, including the various terms and conditions of the stock option exchange. The Tender Offer Statement, including the Offer to Exchange and other related materials, will be available to option holders, at no charge, on the SEC's website at www.sec.gov.

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 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 quarterly report on Form 10-Q for the quarter ended June 30, 2023, which is available on the SEC'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.

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