# HOOKIPA Pharma Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Business Highlights

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- Best-in-class preliminary Phase 2 data for HB-200 in combination with pembrolizumab in patients with recurrent/metastatic HPV16+ head and neck cancers in the first line setting
  - Expect updated Phase 2 data with additional patients in Q2 2024; Company will also provide pivotal trial design and development strategy

- Finalizing Investigational New Drug (IND)-enabling activities for HB-700 for treatment of KRAS mutated cancers
  - IND submission is on track for filing by April 2024, which would trigger a milestone payment from collaboration partner

- Gilead-partnered infectious disease programs progressing on schedule
  - IND clearance achieved for HB-500 for treatment of HIV in Q4 2023; Clinical trial on track to start in Q2 2024, first patient dosed includes associated milestone payment

- Strong cash position at year end 2023 of $117.5 million that reflects more than $71 million gross proceeds from capital raises and $15 million from collaboration-based milestones in 2023

NEW YORK and VIENNA, Austria, March 22, 2024 (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 fourth quarter and full year 2023.

"It was a defining year for HOOKIPA as we witnessed the powerful potential of our novel arenaviral immunotherapies in action. Our HB-200 program delivered potentially best-in-class T cell activation and clinical activity, as this program, in combination with pembrolizumab, showed doubled objective response rate compared to historical standard of care treatment alone," said Joern Aldag, Chief Executive Officer of HOOKIPA. "Our progress last year has positioned us to execute in a meaningful way in 2024. Our data enable us to potentially bring a drug to patients who need new treatment options. We are excited for what is ahead for HOOKIPA, and we look forward to sharing more very soon."

**Business Highlights and Recent Developments**

*Oncology*

- HB-200 in combination with pembrolizumab: positive preliminary Phase 2 data in patients with recurrent/metastatic HPV16+ head and neck cancers in the first line setting. Data was initially presented in May 2023 and additional patient data was provided in October at the European Society for Medical Oncology Congress 2023.
  - Data from the ongoing study (NCT04180215), 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.
  - HOOKIPA is preparing to start a randomized Phase 2/3 trial of HB-200 in combination with pembrolizumab in the 1$^{st}$-line setting for patients with recurrent/metastatic HPV16+ head and neck cancers.

- HOOKIPA's HB-700 program is a novel arenaviral immunotherapy for KRAS-mutated cancers, including the five mutations that are the primary causes of lung, pancreatic and colon cancers.
  - On January 25, 2024, the Company received notification from Roche of their decision to terminate the collaboration and licensing agreement for HOOKIPA's HB-700 program. To date, HOOKIPA has met all go-forward criteria under the agreement and remains eligible for a final milestone payment associated with IND submission. HB-700 is on-track to an expected IND application filing by April 2024.
  - Effective April 25, 2024, HOOKIPA will regain full control of the associated intellectual property portfolio and have full collaboration and licensing rights for this program.

- HOOKIPA enrolled the dose escalation cohorts in the Phase 1/2 study of HB-300 (NCT05553639) for the treatment of advanced prostate cancer.
  - The Study Safety Committee deemed that HB-300 was generally safe and well-tolerated in both dose escalation cohorts.
  - Initial analysis of target antigen-specific T cell responses—using direct ELISPOT without pre-expansion of T

cells—in ten patients between dose level 1 (N=5) and dose level 2 (N=5) indicated a 15- to 26-fold increase of target antigen specific T cells in 30 percent of patients (3/10).
    - In line with its previously announced strategy to prioritize the development of HB-200, the Company has terminated the Phase 1/2 study of HB-300 and will utilize the associated capital and resources for the advancement of its HB-200 program. HOOKIPA will keep the IND open to allow the potential for further development of this program in the future.
    - HOOKIPA will publish the final data at a scientific conference, once complete.

*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 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 (NCT05770895) is 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.

- In November, HOOKIPA's HB-500 program, an investigational therapeutic vaccine for the treatment of human immunodeficiency virus (HIV), also partnered with Gilead, received FDA clearance of its IND application.
    - Also in November, *Nature Partner Journals Vaccines*, published peer-reviewed preclinical data for the program. Data show that HB-500 was well tolerated and generated robust, high-quality and durable immune responses (antigen-specific T cells and antibodies) in non-human primates; and the arenaviral therapeutic vaccination significantly reduced SIV viral load and clinical illness in those animals compared to placebo.
    - HOOKIPA expects to initiate a Phase 1 clinical study of HB-500 in people with HIV in the second quarter of 2024. Under the collaboration agreement with Gilead, HOOKIPA is eligible for a milestone payment upon dosing the first patient in this study.

**Corporate and Financial Updates**

*Corporate Highlights*

- The Company added two new Board Members in 2023: Malte Peters, M.D., in January and Terry Coelho in April.
- Mark Winderlich, Ph.D., will join the Company on April 1, 2024, as Chief Development Officer to lead HOOKIPA's clinical research and development organization.
- On January 29, 2024, HOOKIPA provided an update on its business priorities and oncology partnership programs. The Company announced that it will focus its resources in two strategic areas: (1) prioritize the clinical development of a randomized trial for its HB-200 program and (2) its two Gilead-partnered infectious disease cure programs for hepatitis B and human immunodeficiency virus. As part of its strategic refocus, HOOKIPA will pause development activities related to HB-300 and most of its preclinical research activities. The Company also announced that it will regain full control of the intellectual property portfolio and will have full collaboration and licensing rights to the HB-700 program for KRAS-mutated cancers from Roche effective April 25, 2024.

*Financial Highlights*

- In January 2023, HOOKIPA achieved a $5.0 million milestone payment under its HB-400 collaboration agreement with Gilead. The success-based milestone payment reflected the Company's completion and delivery of a regulatory support package for Gilead's Phase 1 clinical trial.
- In February 2023, HOOKIPA achieved a $10.0 million milestone payment under its HB-700 collaboration agreement with Roche. The success-based milestone payment reflected the start of the HB-700 manufacturing process to support a Phase 1 clinical trial.
- In June 2023, the Company completed a $50.0 million public offering of common stock and non-voting convertible preferred stock. The financing was completed in parallel with the initial Phase 2 data release for HB-200.
- In December 2023, the Company issued 15 million shares of common stock for approximately $21.25 million, at a price of $1.4167 per share, to Gilead under an amended stock purchase agreement between the companies. HOOKIPA has the right, subject to certain terms and conditions, to sell an additional approximately $8.75 million of common stock to Gilead as pro-rata participation in potential future equity raises.

**Anticipated Catalysts & Milestones**

| Program | Indication | Upcoming Anticipated Catalysts |
|---|---|---|
| ***Oncology Programs*** | | |

| | | |
|---|---|---|
| **HB-200** | HPV16+ HNSCC | • Additional Phase 2 first-line data for HB-200 in combination with pembrolizumab (2Q 2024)<br>• Announcement of pivotal trial design post FDA-feedback (2Q 2024)<br>• Pivotal study start 2024 |
| **HB-700** | KRAS | • IND submission, milestone payment (April 2024)<br>• Publication of preclinical data (2Q 2024) |

| ***Infectious Disease Programs: Gilead-Partnered*** | | |
|---|---|---|
| **HB-400** | HBV | • Gilead-led: Phase 1b actively enrolling<br>• Next milestone: Initiation of Phase 2 (timing determined by Gilead) |
| **HB-500** | HIV | • Initiation of Phase 1 trial; first patient dosed and associated milestone payment (2Q 2024) |

**Fourth Quarter and Full Year 2023 Financial Results**

**Cash Position:** HOOKIPA's cash, cash equivalents and restricted cash as of December 31, 2023 was $117.5 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 and the Gilead stock purchase in December 2023, partly offset by cash used in operating activities.

**Revenue:** Revenue was $7.4 million and $20.1 million for the three and twelve months ended December 31, 2023, respectively, compared to $7.8 million and $14.2 million for the same periods in 2022. The increase for the twelve months ended December 31, 2023 was primarily due to higher partial recognition of the upfront and milestone payments under the Gilead and Roche collaborations and 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. The decrease for the three months ended December 31, 2023 was primarily due to a $5.0 million research milestone that was recognized upon achievement related to the Gilead collaboration agreement, partially offset by higher partial recognition of the upfront and milestone payments under the Gilead and Roche collaborations.

**Research and Development Expenses:** HOOKIPA's research and development expenses were $21.2 million and $86.4 million for the three and twelve months ended December 31, 2023, respectively, compared to $17.6 million and $68.6 million for the same periods in 2022. The primary drivers of the increase in research and development expenses were higher clinical study expenses for the HB-200 program and increased spending for the HB-700 program.

**General and Administrative Expenses:** General and administrative expenses amounted to $4.4 million and $18.6 million for the three and twelve months ended December 31, 2023, respectively, compared to $3.8 million and $18.8 million for the same periods in 2022.

**Impairment Expenses:** Impairment expenses amounted to $12.8 million for the three and twelve months ended December 31, 2023, respectively, and resulted from asset write-offs related to the Company's GMP manufacturing facility project, that was discontinued as part of the Company's strategic refocus and rebalance of its cost structure.

**Net Loss:** HOOKIPA's net loss was $24.8 million and $81.6 million for the three and twelve months ended December 31, 2023, respectively, compared to $12.3 million and $64.9 million for the same periods in 2022. This increase was primarily due to an increase in research and development expenses and the impairment of the GMP manufacturing facility project.

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

| | Three months ended December 31, (unaudited) | | 12 months ended December 31, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Revenue from collaboration and licensing | $ 7,407 | $ 7,828 | $ 20,129 | $ 14,249 |
| Operating expenses: | | | | |
| Research and development | (21,162) | (17,592) | (86,424) | (68,645) |
| General and administrative | (4,373) | (3,824) | (18,633) | (18,759) |
| Impairment expense | (12,766) | - | (12,766) | - |
| Total operating expenses | (38,301) | (21,416) | (117,823) | (87,404) |
| Loss from operations | (30,894) | (13,588) | (97,694) | (73,155) |
| Total interest, other income and taxes, net | 6,077 | 1,277 | 16,114 | 8,240 |
| Net loss | $ (24,817) | $ (12,311) | $ (81,580) | $ (64,915) |
| Net loss per share — basic and diluted | (0.22) | (0.17) | (0.86) | (0.99) |

**Condensed Balance Sheets (Unaudited)**
**(In thousands)**

| | As of December 31, 2023 | As of December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and restricted cash | $ 117,521 | $ 113,444 |
| Total assets | 161,337 | 170,454 |
| Total liabilities | 71,480 | 67,937 |
| Total stockholders' equity | 89,857 | 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, KRAS-mutated cancers, and other undisclosed programs. 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," "will," "would" or similar expressions and the negative of those terms. Forward-looking statements in this press release include HOOKIPA's statements regarding the potential of its product candidates to positively impact quality of life and alter the course of disease in the patients it seeks to treat, HOOKIPA's plans, strategies, expectations and anticipated milestones for its preclinical and clinical programs, including the timing of initiating clinical trials and patient enrollment, the availability and timing of results from preclinical studies and clinical trials, the timing of regulatory filings, the expected safety profile of HOOKIPA's product candidates, and expected capital requirements. 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-700, HB-400 and HB-500, 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, HOOKIPA's ability to achieve the expected benefits of its strategic reprioritization. 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, 2023, 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 https://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, www.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.

For further information, please contact:

**Investors & Media**
Michael Kaiser
michael.kaiser@hookipapharma.com
+1 (917) 984 7537