# HOOKIPA Reports Fourth Quarter and Full Year 2021 Financial Results and Provides 2022 Outlook

March 24, 2022

- Lead oncology candidate HB-200 demonstrated high antigen-specific T cell responses and encouraging anti-tumor activity in heavily pre-treated head and neck cancer patients
- HOOKIPA received FDA Fast Track designation and advanced HB-200 to Phase 2 trial in combination with pembrolizumab, with data anticipated in H2 2022
- HOOKIPA and Gilead agreed to advance partnered HIV program, triggering $54 million commitment from Gilead
- Strong 2021 year-end pro forma cash position of $156.9 million when giving effect to payments received in Q1 2022 from Gilead transaction and proceeds of $75 million public follow-on offering

NEW YORK and VIENNA, Austria, March 24, 2022 (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 2021, as well as outlook for 2022.

"As we work to introduce a new class of novel arenaviral immunotherapies, we're proud of the progress we made in 2021. Our data presentations, including at premier oncology meetings, continued to expand the body of evidence on the ability of our technology to induce potent T cell responses, drive tumor regression and potentially serve as a synergistic combination with other immunotherapies," said Joern Aldag, Chief Executive Officer at HOOKIPA. "With the recent capital raise from new and existing top-tier investors, as well as funding from our Gilead collaboration, our cash position provides funding into the first half of 2024, enabling us to advance our novel portfolio. This includes our Phase 2 HB-200 program in combination with pembrolizumab in multiple treatment settings for head and neck cancer and two planned IND applications, one in prostate cancer and the other for Hepatitis B, in collaboration with Gilead. We're excited to grow the value proposition even further for our versatile arenaviral technology in addressing unmet needs in cancer."

**Oncology Portfolio**

- **Interim Phase 1 data highlight promise of HB-200 as a novel immunotherapy for head and neck cancers.**
  - In November, HOOKIPA reported interim data from the ongoing Phase 1 dose escalation study (NCT04180215) showing HB-200 (either as sequential HB-201 or alternating two-vector HB-202/HB-201) rapidly induced high levels of tumor-specific CD8+ T cells considered to be necessary for response, with a favorable tolerability profile and promising, early anti-tumor activity. In heavily pre-treated patients with Human Papillomavirus 16-positive (HPV16+) squamous cell head and neck cancers (HNSCC), HB-200 demonstrated a 75 percent disease control rate and shrinkage of target lesions in 53 percent of patients. The clinical data were consistent with data presented as a late-breaker abstract in March at the American Association of Clinical Research and data presented as an oral presentation in June at the American Society of Clinical Oncology.
  - Based on these data, HOOKIPA initiated a Phase 2 trial to assess HB-200 in combination with pembrolizumab as 1$^{st}$-line and 2$^{nd}$-line treatment for HNSCC; the first patient was dosed in January 2022 and preliminary data is anticipated in the second half of 2022.
  - In November 2021, the Food and Drug Administration granted Fast Track designation to HB-200 in combination with pembrolizumab for the treatment of 1$^{st}$-line advanced HPV16+ HNSCC
- **HOOKIPA prioritizes oncology pipeline based on strength of HB-200 results.** HOOKIPA also announced in November 2021 that it is focusing future research and development in oncology; advancing its immuno-oncology pipeline with HB-300 for prostate cancer and HB-700 for KRAS-mutated colorectal, pancreatic and lung cancers; and evaluating combinations of HB-200 with other oncology treatment modalities. HOOKIPA expects to file an Investigational New Drug (IND) application for HB-300 in the third quarter of 2022.
- **Potential of novel arenaviral platform technology in cancer validated by publications in *Cell Reports Medicine, Nature Communications,* and *Frontiers in Oncology*.**
  - Pre-clinical data published in the March 2021 issue of *Cell Reports Medicine* showed HOOKIPA's alternating 2-vector immunotherapy induced tumor-specific responses exceeding 50 percent of circulating CD8+ T cells and resulted in tumor cures and long-term immunity in a pre-clinical setting for both oncoviral antigens and a cancer

self-antigen. The data provide the scientific substantiation for the ongoing HB-200 program in HPV16+ cancers, as well as the HB-300 program in prostate cancer.
    - In August, *Nature Communications* published pre-clinical data demonstrating that a single administration of HOOKIPA's arenaviral vector was able to modulate the tumor microenvironment and induce potent melanoma self-antigen specific T cell responses, resulting in tumor regression and tumor eradication in 60 percent of mice.
    - A comprehensive review article published in the October issue of *Frontiers in Oncology* reinforced the potential of HOOKIPA's versatile and differentiated arenavirus platform as a promising strategy to elicit potent, tumor-specific T cell responses and address critical unmet needs in cancer treatment.

- **Clinical collaboration to evaluate HB-200 with pembrolizumab underscores broad potential for additive benefits in combination with current standard of care and novel agents to improve anti-tumor immune response.** In September, HOOKIPA announced it entered into a clinical collaboration and supply agreement with Merck & Co., Inc., Kenilworth, NJ, USA (known as Merck MSD outside of the United States and Canada) to evaluate the combination of HB-200 with pembrolizumab. HOOKIPA plans to initiate a randomized Phase 2 trial of HB-200 in combination with pembrolizumab in the first half of 2023.

**Infectious Disease Portfolio**

- **Collaboration with Gilead Sciences advances development of functional cures for Hepatitis B virus (HBV) and Human Immunodeficiency virus (HIV).**
    - In November, HOOKIPA announced that its research collaboration with Gilead to develop a potential functional cure for HBV successfully passed Gilead's Request for Development milestone. Gilead plans to progress the program to IND-enabling stage in 2022 to support IND filing for the arenavirus vector combination.
    - In February 2022, HOOKIPA and Gilead agreed to advance its partnered HIV program, triggering a $54 million commitment from Gilead. HOOKIPA assumed development responsibility for the HB-500 program through the completion of a Phase 1b clinical trial; Gilead has the exclusive right for further development thereafter. Financial terms included a $4 million preclinical milestone, a $15 million non-refundable initiation fee and $35 million equity commitment at a premium to market price. The $35 million equity commitment includes a first tranche of $5 million (purchased at a $3 share price on February 15) and the remaining $30 million can be drawn at a 30 percent premium in a second tranche or at market price in a third tranche. If Gilead pursues further development, HOOKIPA is entitled to potential development and sales milestone payments exceeding $237 million, as well as royalties on net product sales.

- **Positive updated interim Phase 2 data reported on HB-101 for Cytomegalovirus (CMV) in kidney transplant patients.** In November, HOOKIPA shared updated interim data from the ongoing Phase 2 clinical trial (NCT03629080) of HB-101, a prophylactic CMV vaccine candidate. These data showed three doses of HB-101 were generally well tolerated, elicited strong immunogenicity, and reduced incidence of CMV viremia, consistent with results reported in November 2020. Final results are anticipated in 2023 once the 80 enrolled patients complete their 12-month observation period following kidney transplantation. HOOKIPA is pursuing partnership opportunities for continued development, as part of its updated corporate strategy to prioritize the oncology pipeline opportunities.

**Corporate Updates**

- Klaus Orlinger, Ph.D. has been promoted from Executive Vice President, Research to Chief Scientific Officer. Klaus joined HOOKIPA in 2012 and has played a leading role in the development of novel arenaviral immunotherapies and advancing them to the clinic.
- To express their confidence in and excitement about the Company, the executive team agreed to receive 50 percent of its 2021 bonus in the form of an options grant at $3 per share. Executive team members also waived portions of their salaries for the first half of 2022 in exchange for shares valued at $3 per share; the CEO waived 50 percent of his first half 2022 salary and other executives waived 20 percent each.

**Upcoming Milestones**

- Phase 1 HPV16+ monotherapy data: Mid-2022
- Phase 2 HPV16+ combination data in HNSCC
    - 1$^{st}$-line initial data: 2H 2022
    - 2$^{nd}$-line initial data: 2H 2022
    - Randomized Phase 2 in 1$^{st}$ line start with pembrolizumab: 1H 2023 (Fast Track designation)
- Prostate cancer IND: 3Q 2022
- Hepatitis B therapeutic IND: 2022 (Gilead-led)

**Fourth Quarter and Full Year 2021 Financial Results**

**Cash Position:** HOOKIPA's cash, cash equivalents and restricted cash as of December 31, 2021 was $66.9 million compared to $143.2 million as of December 31, 2020. When giving effect to (i) receipt of a $15.0 million initiation payment and the issuance of 1,666,666 shares of our common stock for an aggregate purchase price of $5.0 million pursuant to an agreement with Gilead in February 2022, and (ii) the net proceeds of $70 million from the issuance of common stock and convertible preferred stock in a follow-on financing in March 2022, HOOKIPA's pro-forma cash, cash equivalents and restricted cash as of December 31, 2021 would have been $156.9 million.

Revenue was $3.9 million for the three months ended December 31, 2021, and $18.4 million for the year ended December 31, 2021 compared to $5.2 million for the three months ended December 31, 2020 and $19.6 million for the year ended December 31, 2020. The decrease was primarily due to lower revenue from research milestones and lower recognition of deferred revenue related to upfront and milestone payments under the Collaboration Agreement with Gilead.

**Research and Development Expenses:** HOOKIPA's research and development expenses were $22.4 million for the three months ended December 31, 2021, and $82.9 million for the year ended December 31, 2021 compared to $15.7 million for the three months ended December 31, 2020, and $54.8 million for the year ended December 31, 2020.

The primary drivers of the increase in research and development expenses by $28.1 million compared to 2020 were an increase in manufacturing and quality control expenses of $9.9 million, an increase in clinical study expenses of $3.2 million, along with an increase in other direct expenses and laboratory expenses of $8.1 million and an increase in internal research and development expenses of $6.9 million. The increase was mainly due to the progress in the clinical trial of our HB-200 program, particularly, the increased patient recruitment and related clinical trial monitoring and testing activities, as well as manufacturing and quality control work in preparation of a further extension of the trial. Manufacturing and quality control expenses were also driven by the progress towards clinical development in our Gilead partnered programs and other preclinical programs.

**General and Administrative Expenses:** General and administrative expenses amounted to $3.5 million for the three months ended December 31, 2021 and $17.3 million for the year ended December 31, 2021 compared to $4.7 million for the three months ended December 31, 2020, and $18.1 million for the year ended December 31, 2020. The decrease was primarily due to a decrease in personnel-related expenses and a decrease in other general and administrative expenses, partially offset by an increase in professional and consulting fees.

**Net Loss:** HOOKIPA's net loss was $21.2 million for the three months ended December 31, 2021 and $75.7 million for the year ended December 31, 2021 compared to a net loss of $12.5 million for the three months ended December 31, 2020 and $44.1 million for the year ended December 31, 2020. This increase was primarily due to an increase in research and development expenses, mainly driven by the progression of HOOKIPA's oncology programs, in particular the clinical trial of the HB-200 program.

**Conference call:** HOOKIPA will host a conference call and live webcast at 8:30 am EST today to discuss its financial results and provide a corporate update.

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|---|---|
| Dial In: | +1 877 870 9135 |
| UK Dial In: | 0800 279 6619 |
| Austria Dial In: | +43 (0)1 928 4090 |
| Conference ID: | 1868118 |
| Webcast: | Link |

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 focused on developing novel immunotherapies, based on its proprietary arenavirus platform, that 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+ cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly-owned investigational arenaviral immunotherapeutics targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), 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.

**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, 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 annual report on Form 10-K for the year ended December 31, 2021 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, (unaudited) | | Year ended December 31, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Revenue from collaboration and licensing | $ 3,895 | $ 5,163 | $ 18,448 | $ 19,584 |
| Operating expenses: | | | | |
| Research and development | (22,419) | (15,688) | (82,853) | (54,787) |
| General and administrative | (3,523) | (4,669) | (17,269) | (18,082) |
| Total operating expenses | (25,942) | (20,357) | (100,122) | (72,869) |
| Loss from operations | (22,047) | (15,194) | (81,674) | (53,285) |
| Total interest, other income and taxes, net | 812 | 2,719 | 6,009 | 9,203 |
| Net loss | $ (21,235) | $ (12,475) | $ (75,665) | $ (44,082) |
| Net loss per share — basic and diluted | (0.65) | (0.46) | (2.30) | (1.69) |

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

| | **As of December 31, 2021** | **As of December 31, 2020** |
|---|---|---|
| Cash, cash equivalents and restricted cash | $ 66,912 | $ 143,177 |
| Total assets | 126,045 | 187,817 |
| Total liabilities | 36,453 | 31,694 |
| Total stockholders' equity | 89,592 | 156,123 |

For further information, please contact:


**Media enquiries**
Instinctif Partners
hookipa@instinctif.com
+44 (0) 7457 2020

**Investors**
Matt Beck
Executive Director - Investor Relations
matthew.beck@hookipapharma.com