

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 7, 2020

**HOOKIPA PHARMA INC.**

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-38869  
(Commission  
File Number)

81-5395687  
(IRS Employer  
Identification No.)

350 Fifth Avenue, 72nd Floor, Suite  
7240  
New York, New York  
(Address of principal executive offices)

10118  
(zip code)

Registrant's telephone number, including area code: +43 1 890 63 60

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class    | Trading Symbol(s) | Name of exchange on which registered |
|------------------------|-------------------|--------------------------------------|
| Common stock, \$0.0001 | HOOK              | The Nasdaq Global Select Market      |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On December 7, 2020, HOOKIPA Pharma Inc. (the “Company”) announced positive interim data from its ongoing Phase 1 clinical trial of HB-201, its replicating monotherapy candidate for the treatment of HPV16+ cancers. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of Form 8-K, including the accompanying Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

During a conference call and webcast scheduled to be held at 8:30 a.m. Eastern Time on December 7, 2020, the Company’s management will discuss the Phase 1 data for HB-201. The slide presentation for the conference call and webcast is filed as Exhibit 99.2 hereto and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| <b>Exhibit Number</b> | <b>Description</b>   |
|-----------------------|--|
| <a href="#">99.1</a>  | <a href="#">Press release issued by HOOKIPA Pharma Inc. on December 7, 2020</a>  |
| <a href="#">99.2</a>  | <a href="#">HOOKIPA Pharma Inc. Investor Presentation dated December 7, 2020</a> |

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HOOKIPA Pharma Inc.

Date: December 7, 2020

By: /s/ Jörn Aldag  
Jörn Aldag  
Chief Executive Officer  
(Principal Executive Officer)



**HOOKIPA Interim Phase 1 Monotherapy Data of HB-201 for the Treatment of Advanced HPV16<sup>+</sup> Cancers Shows Promising Anti-Tumor Activity and Favorable Tolerability**

- Results support first proof of concept for HOOKIPA's replicating investigational single-vector immunotherapy in oncology
- Data demonstrate responses and stable disease in some head and neck cancer patients who all received at least two prior therapies and progressed on a PD1 inhibitor
- By targeting an antigen common to Human Papillomavirus 16-positive (HPV16<sup>+</sup>), HB-201 has the potential to be a tumor-agnostic therapy for all HPV16<sup>+</sup> cancers

**New York, US and Vienna, Austria**, December 7, 2020 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced positive interim Phase 1 data on HB-201, its replicating monotherapy for the treatment of HPV16<sup>+</sup> cancers. The results are from the initial dose escalation cohorts of an ongoing Phase 1/2 clinical trial (NCT04180215) evaluating HB- 201 as therapy for patients with advanced HPV16<sup>+</sup> metastatic cancers. HOOKIPA will host a conference call and live audio webcast today at 8:30am EST.

These interim data support proof of concept for HB-201 monotherapy as a new immunotherapy for a difficult-to-treat patient population with multiple prior treatment failures. As of December 4, 2020, 22 patients have been enrolled in the first two cohorts, of which 15 were eligible for evaluation. Among the 15 evaluable patients, 11 patients had relapsed/refractory metastatic squamous cell head and neck cancer (HNSCC), all of whom had progressed on prior therapy with a PD1 inhibitor. As per RECIST1.1, in patients with third-line or later HNSCC, HB-201 demonstrated an unconfirmed response rate of 18% (one unconfirmed complete responder and one unconfirmed partial responder) and a 73% disease control rate (six stable disease patients, in addition to the two unconfirmed responses referenced above).

Median progression-free survival (mPFS) is currently measured at 72 days and is ongoing. Although not demonstrated in a head-to-head trial, these HB-201 results, in more heavily treated patients who progressed on a PD1 inhibitor, compare favorably to the benchmark data of a 13% overall response rate and a 60-day mPFS<sup>1</sup> for nivolumab in second-line PD1 inhibitor naïve HNSCC patients, based on data published from the third-party registrational study.

Encouraging efficacy signals were also seen in the more heterogeneous group of all 15 evaluable patients with HPV16<sup>+</sup> cancers treated in this trial, comprised of the 11 HNSCC patients summarized above and four other patients with HPV16<sup>+</sup> cervical, anal, or vaginal tumors. In these 15 patients, HB-201 demonstrated an unconfirmed response rate of 13%, a disease control rate of 67%, and a median PFS that is also ongoing and currently measured at 72 days.

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<sup>1</sup> Ferris R et al. Nivolumab for recurrent squamous-cell carcinoma of the head and neck. *N Engl J Med*. 2016; 375:1856-1867.

“We are thrilled by these preliminary HB-201 data, as they show the potential of our arenavirus platform in oncology and represent future possible therapeutic options for patients with HPV16<sup>+</sup> cancers,” said Joern Aldag, Chief Executive Officer of HOOKIPA. “The early response with our single-vector HB-201 therapy highlights the potential of our replicating technology, especially as we explore alternating two-vector therapy with HB-201/HB-202, and a future combination with a PD-1 inhibitor, both of which we hope will deliver even greater responses.”

Of the 22 patients enrolled on the trial as of December 4<sup>th</sup>, preliminary safety data show that HB-201 has been well tolerated. Treatment-related adverse events were reported by 41% of participants. Almost all reported events were Grade 1 and 2 and included fatigue, fever, decreased appetite, constipation, nausea, and itching. Only one serious adverse event deemed related to HB-201, Grade 3 fatigue leading to hospitalization, has been reported to-date. The rate of adverse events was consistent regardless of administration route.

“There remains a considerable unmet need in the treatment of HPV16<sup>+</sup> cancers, particularly those in head and neck, and these preliminary data on HB-201 as a monotherapy are encouraging,” said Alan L. Ho, MD, PhD, a medical oncologist at Memorial Sloan Kettering Cancer Center and an investigator on the trial.

#### **About the trial**

This Phase 1/2 clinical trial is an open-label dose-escalation and dose-expansion trial in individuals with treatment-refractory HPV16<sup>+</sup> cancers. The primary endpoint of the Phase 1 trial is a recommended Phase 2 dose based on safety and tolerability. Secondary endpoints include anti-tumor activity as defined by RECIST 1.1, immunogenicity, safety, and tolerability.

The trial is designed to evaluate different dose levels of HB-201 as a single-vector therapy, as an alternating two-vector therapy together with HB-202, and in combination with a PD-1 inhibitor. Dosing frequencies of every three weeks and every two weeks are being explored during dose escalation.

Since the trial opened in December 2019, 22 patients with metastatic HPV16<sup>+</sup> tumors have been enrolled in the HB-201 monotherapy segment: 17 with squamous cell head and neck tumors, two with cervical, one with nasopharyngeal, one with anal, and one with vaginal. Patients had received at least two prior therapies, and most patients progressed on a PD-1 inhibitor, a platinum-containing regimen or both. Enrollment is ongoing and HOOKIPA expects to share additional interim clinical data from the HB-201/HB-202 alternating two-vector therapy segment in mid-2021.

#### **About HB-201/HB-202**

HB-201 and HB-202 are engineered using HOOKIPA's replicating arenaviral vector platform. They are designed to use different arenavirus backbones (LCMV for HB-201 and PICV for HB-202), while expressing the same antigen, an E7/E6 fusion protein derived from HPV16. In pre-clinical studies, alternating administration of HB-202 and HB-201 resulted in a ten-fold increase in immune response and better disease control than either compound alone.

#### **Conference call**

HOOKIPA will host a conference call and live audio webcast today at 8:30am EST to discuss the HB-201 monotherapy data from the interim analysis of the Phase 1 trial. To access the conference call, please dial +1 877 870 9135 (from the US) or +44 2071 928338 (international) and refer to conference ID 9747865. 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.

– END –

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### **About Human Papillomavirus**

Human Papillomavirus, or HPV, is estimated to cause about 5 percent of the worldwide burden of cancers. This includes approximately 99 percent of cases in cervical, up to 60 percent of head and neck, 70 percent of vaginal and 88 percent of anal cancers.

The majority of these cancers are caused by the HPV serotype 16. Most infections with HPV are cleared from the body with no lasting consequences. However, in some cases, HPV DNA becomes integrated into chromosomal DNA. When host cells take up this DNA, they express the HPV E6 and E7 proteins. This uptake can potentially lead to cancer since expression of these proteins leads to alterations in cell cycle control, which in turn predisposes these cells to become cancerous.

### **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 (VaxWave<sup>®</sup>) and replicating (TheraT<sup>®</sup>), are designed 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, HOOKIPA's replicating arenavirus technology has the potential to induce CD8+T cell response levels previously not achieved by other immuno-therapy approaches.

HOOKIPA's non-replicating prophylactic cytomegalovirus (CMV) vaccine candidate 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.

In addition, 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.

Find out more about HOOKIPA online at [www.hookipapharma.com](http://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-Q for the quarter ended September 30, 2020 which is available on the Security and Exchange Commission's website at [www.sec.gov](http://www.sec.gov) and HOOKIPA's website at [www.hookipapharma.com](http://www.hookipapharma.com).

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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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**HB-200**

**Arenavirus-based Therapeutics for HPV16+ Cancers**

December 7, 2020





This Presentation includes forward-looking statements. All statements other than statements of historical facts contained in these materials or elsewhere, including statements regarding (i) the success, cost, results and timing of HOOKIPA's product development activities and clinical trials; (ii) the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug Application and Biological Licensing Application filings for HOOKIPA's current and future product candidates, and final U.S. Food and Drug Administration, European Medicines Agency or other foreign regulatory authority approval of HOOKIPA's current and future product candidates; (iii) HOOKIPA's ability to develop and advance its current product candidates and programs into, and successfully complete, clinical studies; (iv) HOOKIPA's manufacturing, commercialization and marketing capabilities and strategy; (v) the potential benefits of and HOOKIPA's ability to maintain its collaboration with Gilead Sciences, Inc. and establish or maintain future collaborations or strategic relationships or obtain additional funding; (vi) risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises 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 and (vii) the rate and degree of market acceptance and clinical utility of HOOKIPA's current and future product candidates, are forward-looking statements. Forward-looking statements use words like "believes," "plans," "expects," "intends," "will," "would," "anticipates," "estimates," and similar words or expressions in discussions of the Company's future operations, financial performance or the Company's strategies. These statements are based on current expectations or objectives that are inherently uncertain, especially in the case of an enterprise with limited operating history. In light of these uncertainties, and the assumptions underlying the expectations and other forward-looking statements expressed, the forward-looking events and circumstances discussed in the accompanying materials may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, the occurrence of certain events or otherwise. As a result of these risks and others, actual results could vary significantly from those anticipated in this Presentation, and our financial condition and results of operations could be materially adversely affected. This Presentation contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

# HB-201 Monotherapy Phase 1 Data Shows Promising Anti-Tumor Activity and Favorable Tolerability as Treatment for Advanced HPV16+ Cancers



## HPV16+ Cancer Therapy

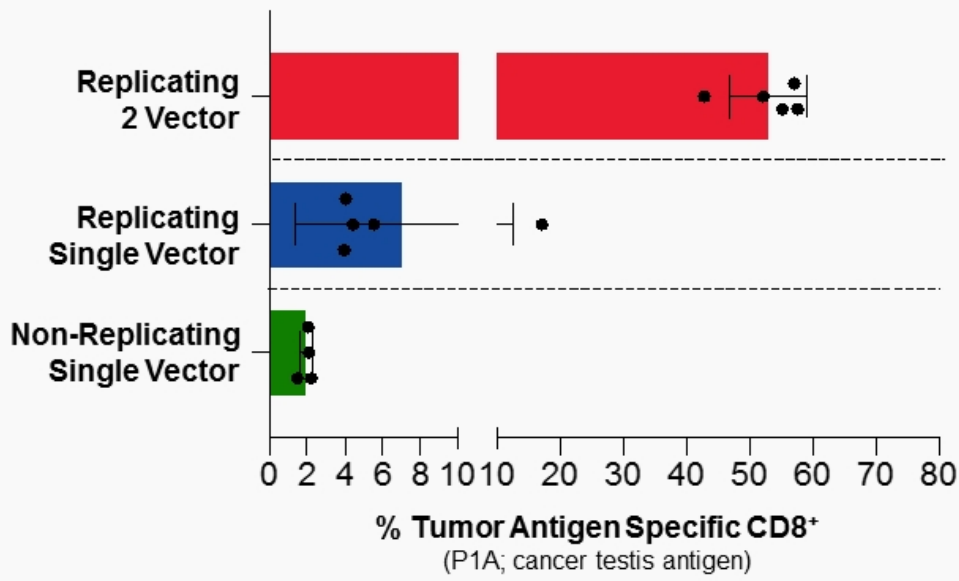
HB-201 Monotherapy  
Early Clinical  
Proof of Concept

HB-201 / HB-202  
Accruing Patients

- **HB-201 monotherapy, a replicating single vector (LCMV<sup>1</sup>) therapy, in advanced metastatic patients, demonstrated<sup>2</sup>:**
  - Favorable tolerability
  - Observed unconfirmed complete response, partial response, and stable diseases
  - Continuing to accrue patients to optimize dose and regimen
- **HB-201 / HB-202, a replicating alternating dual vector therapy with HB-202 (Pichinde virus<sup>3</sup>), entered clinic in October 2020**
- **Will explore combination with checkpoint inhibitor at recommended Phase 2 dose to assess potential in earlier line patients**

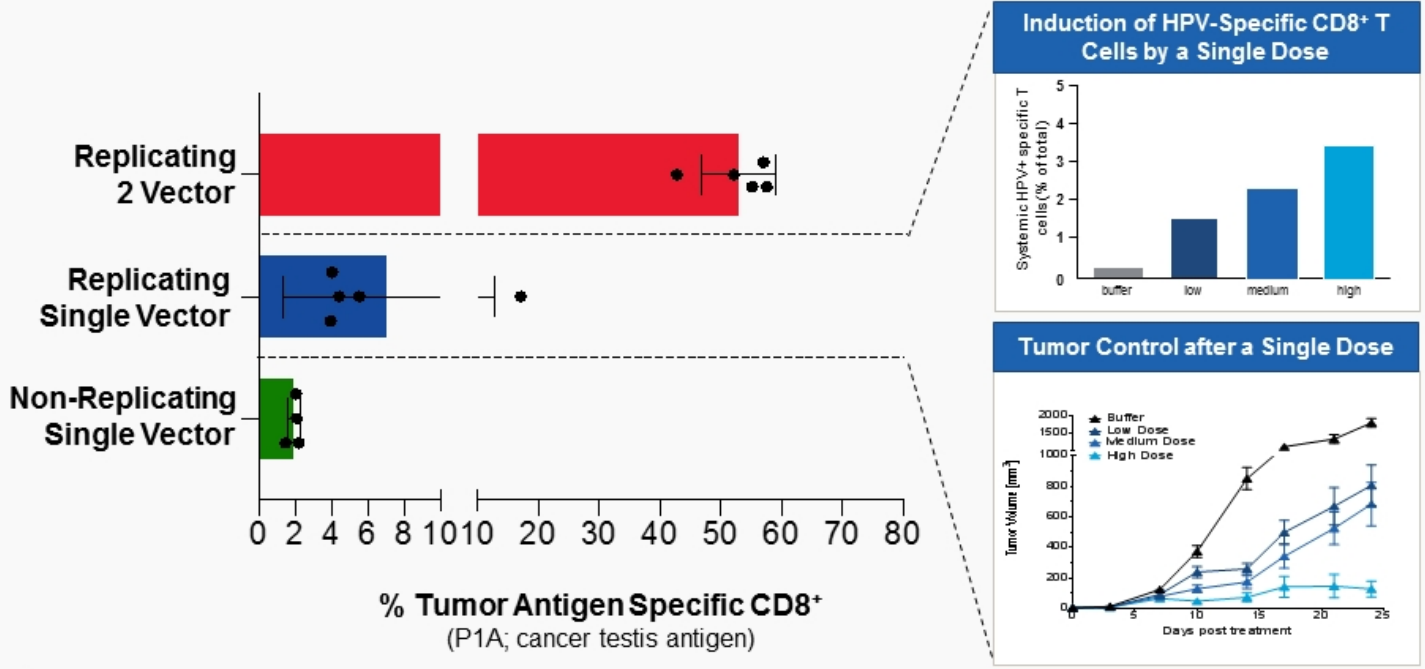
<sup>1</sup>LCMV: Lymphocytic Choriomeningitis Virus; <sup>2</sup>Interim analysis as of December 4, 2020; <sup>3</sup>PICV: Pichinde Virus

# Preclinically, Our Engineered Arenaviruses Create Outstanding T Cell Responses (Up to >50% of CD8<sup>+</sup> T Cells) Against Tumor Self Antigens

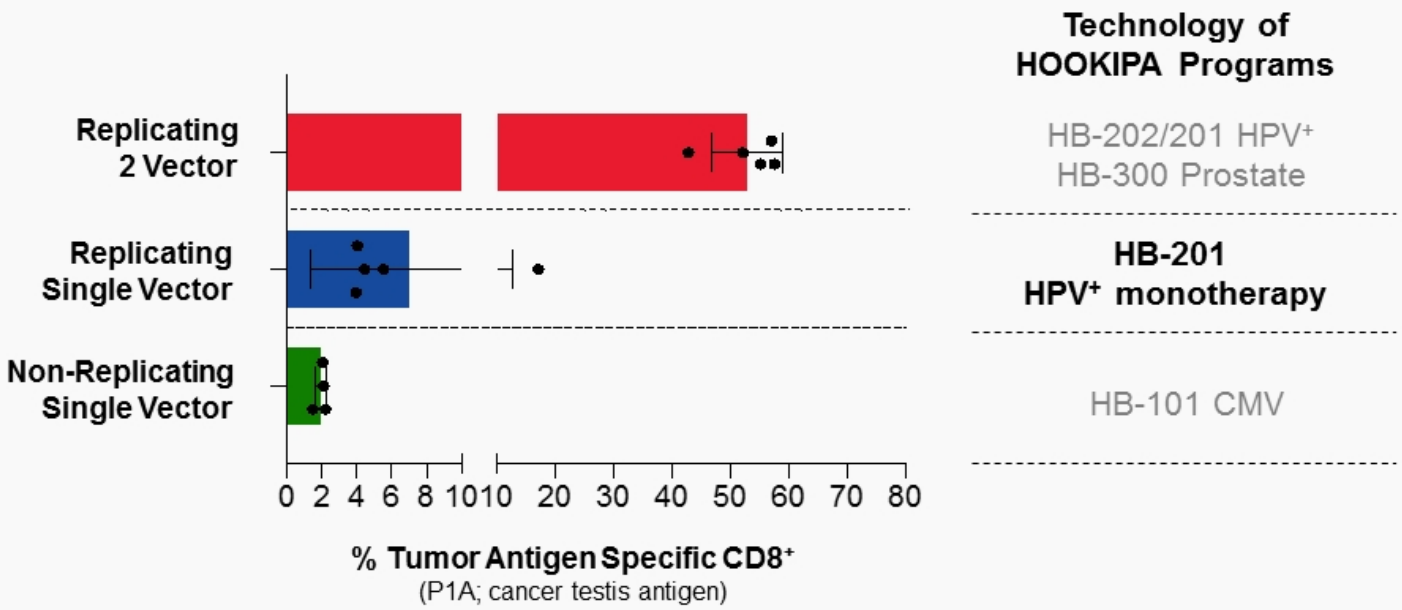


Note: Comparison in mice of Replicating Dual Vector (TheraT<sup>®</sup>) therapy, Replicating Single Vector (TheraT<sup>®</sup>) therapy and Non-Replicating Single Vector (VaxWave<sup>®</sup>) therapy, each expressing the mouse cancer-testis antigen P1A, for their ability to induce P1A-specific CD8<sup>+</sup> T cells.

# Preclinical Studies with Engineered Arenaviruses Showed a Dose-Dependent Correlation Between T Cell Responses and Tumor Control



# Today the Focus Will Be on the Interim Phase 1 Results of HB-201, a Replicating Single Vector Therapy



## HB-201

- **What: Replicating Single Vector** (LCMV) encoding E7/E6 antigen
- **Approach:** Potential **fast path** to registration in advanced metastatic HPV16<sup>+</sup> cancers
  - HB-201 monotherapy may provide greater clinical benefit to current options for at least 3<sup>rd</sup> line metastatic head & neck, 2<sup>nd</sup> line cervical, anal, and other HPV16<sup>+</sup> tumors

## HB-201 / HB-202

- **What: Replicating 2 Vector** (PICV + LCMV) encoding E7/E6 antigen
- **Approach:** Potential **best-in-class** therapeutic for metastatic HPV16<sup>+</sup> cancers
  - Expected to deliver ~10x greater level of antigen-specific T cells to the tumor relative to HB-201 monotherapy, based on preclinical studies
  - Potential for application in first line metastatic HPV16<sup>+</sup> tumors settings

### Group Summaries Tumor Types & Dosing Details

**Group 1:** HB-201 in HPV16+ HNSCC  
Delivery: IV dosing

**Group 2:** HB-201 in HPV16+ cancers accessible for intra-tumoral injection  
Delivery: Initial IT dose followed by repeated doses of IV patient cohorts:

- HNSCC
- Cervical
- Anal
- Penile
- Vaginal
- Vulvar

**Group 3:** Alternating doses of HB-202 & HB-201 in HPV16+ HNSCC  
Delivery: IV dosing

### General Information

**Study endpoints:**

- Primary: Determine a recommended Phase 2 dose
- Secondary: Antitumor activity (via ORR, DCR, duration of response, PFS, and overall survival), safety and tolerability

**Principal Investigator:** David Pfister, MD  
Chief, Head and Neck Oncology Service at  
Memorial Sloan Kettering Cancer Center

**Study milestones:**

- First patient dosed on HB-201: December 2019
- First patient dosed on HB-202/HB-201: October 2020

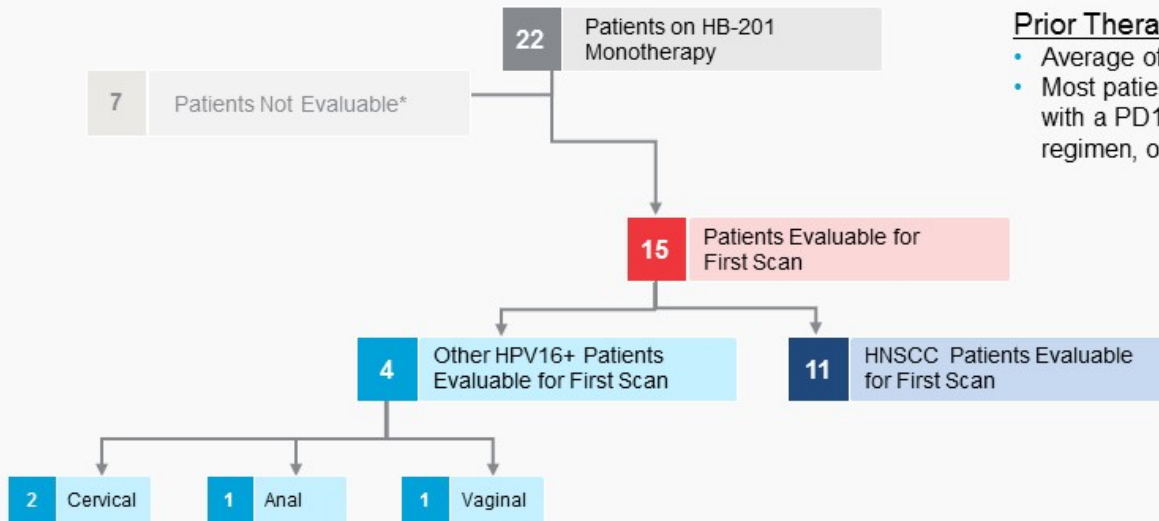
*When open, Group 4 will utilize the alternating vector therapy of HB-202 & HB-201 in HPV16+ cancers accessible for intra-tumoral injection.*

# Heavily Pre-treated Patients with Metastatic HPV16+ Tumors Enrolled into Ongoing Phase 1 Trial



## Prior Therapies

- Average of 3 prior therapies
- Most patients have been pre-treated with a PD1 inhibitor, a platinum regimen, or both



*\*Seven patients total were not evaluable. As detailed on slide 12:  
five patients were ongoing but too early for scans (Pt 22, 21, 18, 17, 3, 1);  
one patient withdrew consent before 1st scan: (Pt 6);  
one patient was judged to be a Clinical Progressor before 1st scan: (Pt 4).*



| Patients with reported AEs                                     | Number of patients reporting / Number of patients treated (%) |
|--|---|
| Treated patients with reported AEs                             | 15 / 22 (68%)   |
| Patients with reported TRAEs                                   | 9 / 22 (41%)  |
| Patients with reported TRAEs related to IV HB-201 <sup>1</sup> | 8 / 22 (36%)  |
| Patients with reported TRAEs related to IT HB-201 <sup>1</sup> | 2 / 7 (29%)   |

### Treatment Related AE Summary:

- 23 unique terms | Highest grade per patient: 38 total events
- 37 Grade 1-2 highest grade events (97%)
- 1 Grade 3 highest grade event / 1 SAE (3%): Grade 3 Fatigue leading to hospitalization

<sup>1</sup>For patients in Group 2 (IT-IV), AEs may be reported as related to HB-201 IT and/or HB-201 IV.

### 3<sup>rd</sup>+ Line Metastatic HNSCC\* Patients (N=11): All progressed on prior PD1 inhibitor

- 1 Pt with Unconfirmed Complete Response
- 1 Pt with Unconfirmed Partial Response (ongoing)
- 6 Pts with Stable Disease

**Unconfirmed  
Response Rate: 18%**

**Disease control rate:  
73%**

**Benchmark data<sup>^</sup>:** 13% ORR for nivolumab monotherapy in 2<sup>nd</sup> Line HNSCC<sup>1</sup>  
48% DCR for nivolumab monotherapy in 2<sup>nd</sup> Line HNSCC<sup>2</sup>

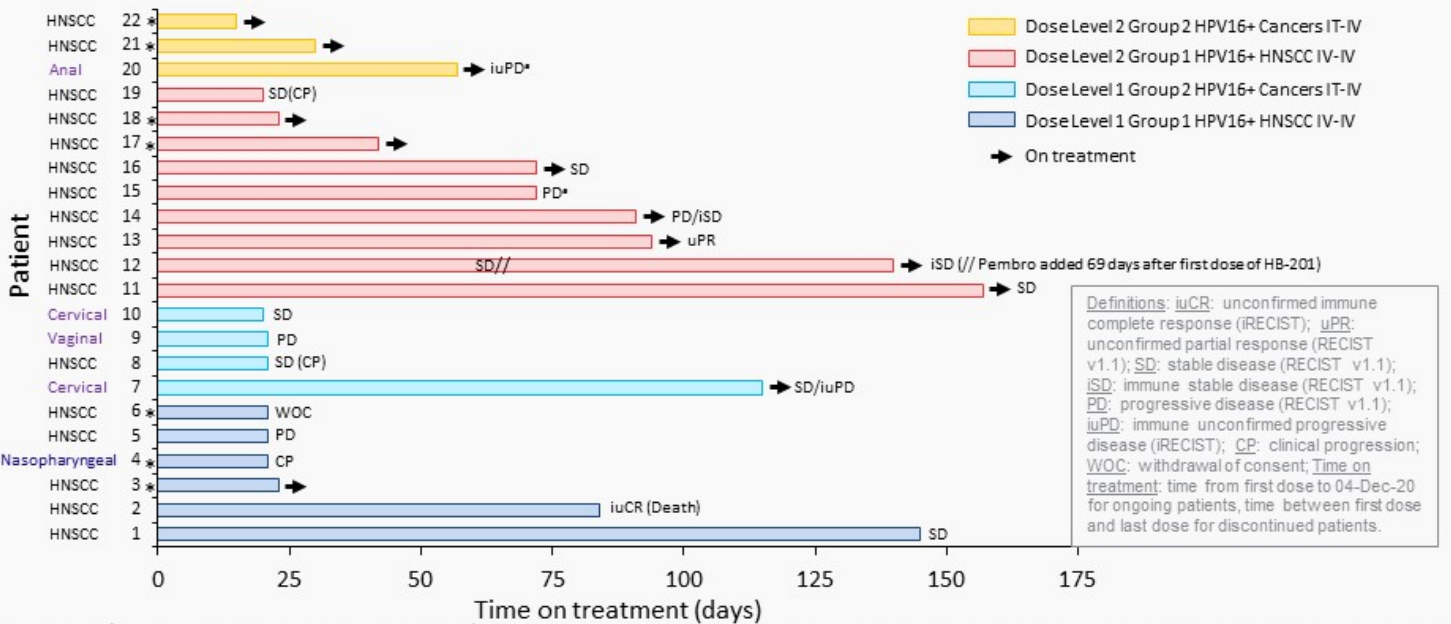
### Among 15 Total Evaluable HPV16+ Patients: Average of 3 prior lines

Patient types: 11 HNSCC (summarized above), and additionally 2 cervical, 1 anal, and 1 vaginal

- Best overall responses: 1 unconfirmed Complete Response, 1 unconfirmed Partial Response, 8 Stable Diseases
- **Unconfirmed Response Rate: 13%**
- **Disease control Rate: 67%**

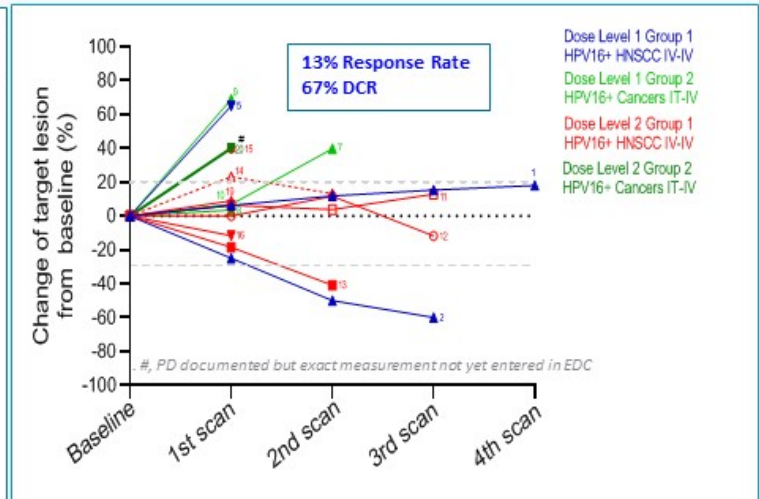
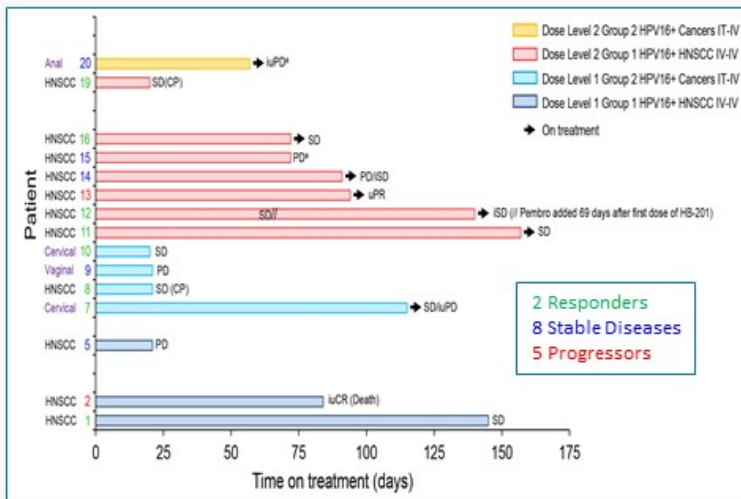
<sup>^</sup>Excluding nasopharyngeal; <sup>1</sup>Historical data, not head-to-head comparisons. ORR=Overall response rate, DCR=disease control rate;  
<sup>2</sup>As reported by third-party conducted registrational trial. Ferris et al, NEJM 2016; 375: 1856-1867. <sup>3</sup>Brahmer et al, JCO 2010, 3169; <sup>4</sup>Botticelli et al, Vaccines 2020.

# HB-201 Monotherapy Efficacy Data: Time on Study and Target Lesion Response For All Treated Patients (N=22)



\* Not evaluable (5 ongoing but too early for scans: Pt 22, 21, 18, 17, 3); 1 WOC before 1st scan: Pt 6; 1 judged to be CP before 1st scan: Pt 4. \* Not yet entered into EDC. CP, clinical progression; WOC, withdrawal of consent. Time on treatment is defined as time from first dose to 04-Dec-20 for ongoing patients and time between first dose and last dose for discontinued patients. At the investigator's discretion, certain patients received their first scans before the recommended 35 days after first administration of study drug.  
HOOKIPA Pharma

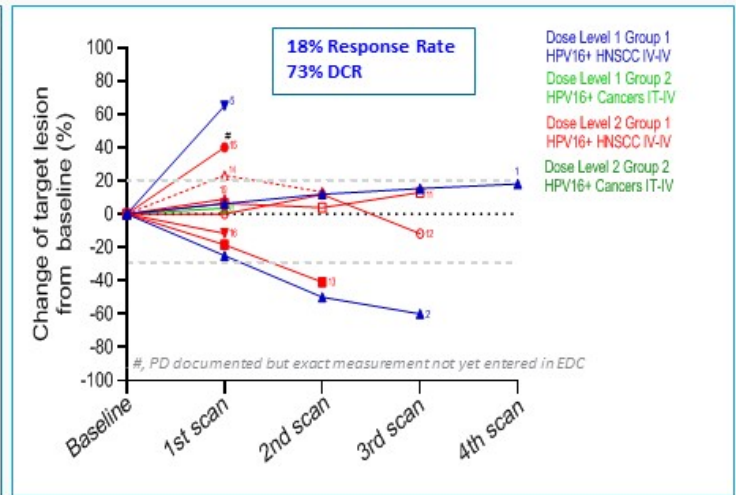
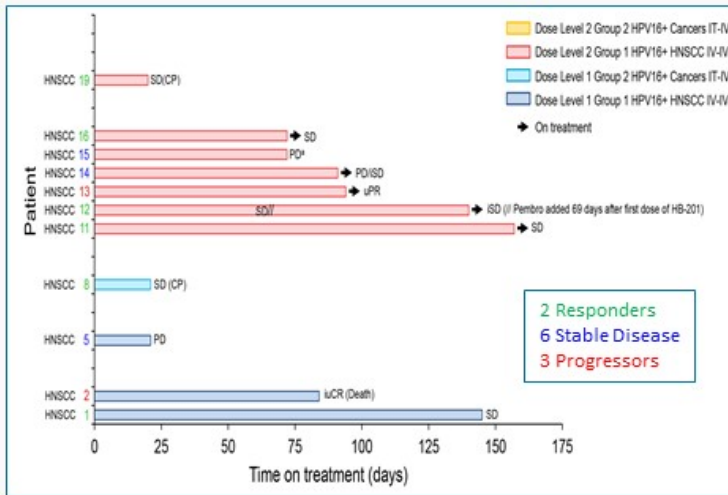
# HB-201 Efficacy Data for Evaluable Patients with HPV16+ Cancers (N=15) Time on Study, Target Lesion Response and Spider Plot of Target Lesion Sum of Diameters



\* Not yet entered into EDC. Definitions: iuCR: unconfirmed immune complete response (iRECIST); uPR: unconfirmed partial response (RECIST v1.1); SD: stable disease (RECIST v1.1); iSD: immune stable disease (RECIST v1.1); PD: progressive disease (RECIST v1.1); iuPD: immune unconfirmed progressive disease (iRECIST); CP: clinical progression; WOC: withdrawal of consent; Time on treatment: time from first dose to 04-Dec-20 for ongoing patients, time between first dose and last dose for discontinued patients. At the investigator's discretion, certain patients received their first scans before the recommended 35 days after first administration of study drug.

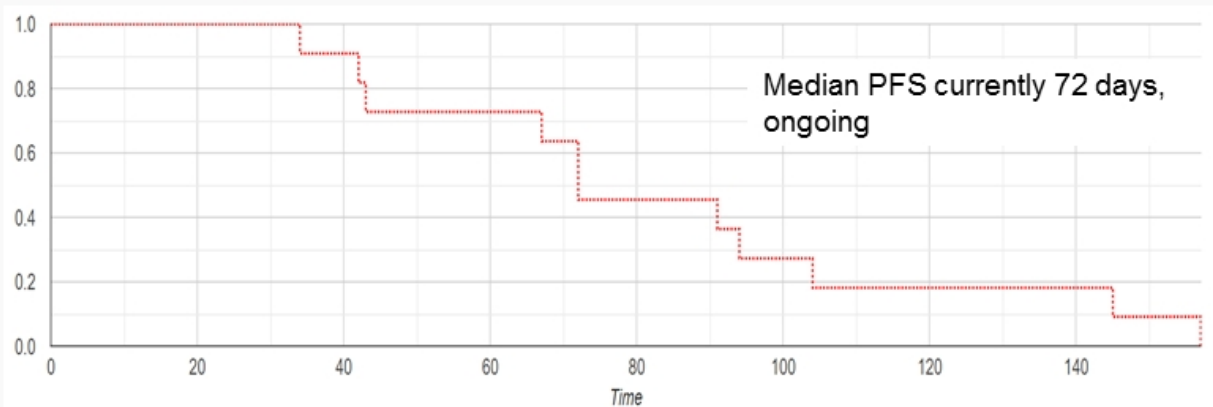
# HB-201 Efficacy Data for Evaluable Patients with HNSCC (N=11)

## Time on Study, Target Lesion Response and Spider Plot of Target Lesion Sum of Diameters



\* Not yet entered into EDC. Definitions: *iuCR*: unconfirmed immune complete response (iRECIST); *uPR*: unconfirmed partial response (RECIST v1.1); *SD*: stable disease (RECIST v1.1); *iSD*: immune stable disease (RECIST v1.1); *PD*: progressive disease (RECIST v1.1); *iuPD*: immune unconfirmed progressive disease (iRECIST); *CP*: clinical progression; *WOC*: withdrawal of consent; *Time on treatment*: time from first dose to 04-Dec-20 for ongoing patients, time between first dose and last dose for discontinued patients. At the investigator's discretion, certain patients received their first scans before the recommended 35 days after first administration of study drug.

## Median Progression Free Survival (PFS) in Evaluable HNSCC Patient Cohort (N=11)



Benchmark data (not head-to-head comparison): 60 day mPFS for Nivolumab Monotherapy in 2<sup>nd</sup> L HNSCC, as reported by third-party conducted registrational trial. Ferris et al, NEJM 2016; 375: 1856-1867.

**Median PFS in All Evaluable HPV16<sup>+</sup> Patient Cohort (HNSCC, Cervical, Anal, Vaginal, N=15) is also currently 72 days and is ongoing.**

# Patient Profile #1: 68-Year-Old Male with HNSCC & Unconfirmed Complete Response (Dose Level 1 IV-IV)

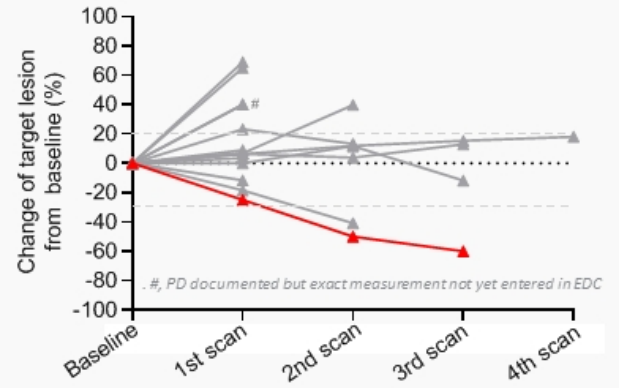
**Prior treatments:** 4 prior lines of therapy

Cisplatin + XRT ► Carboplatin/5-FU/pembrolizumab/paclitaxel  
 ► AO-176 (DC47 inhibitor) ► Pembrolizumab (84 days since last CPI)/Lenvatinib

**Results:** Rapid response with confirmed PR/unconfirmed CR of target lesion (target lesion is a lymph node<sup>1</sup>)

25% reduction by first scan ► 50% by second scan ► 60% by third scan

**Status:** Patient died of pulmonary hemorrhage after 105 days on study (deemed not to be treatment related)



C, cycle; CPI, checkpoint inhibitor; D, day; FU, fluorouracil; XRT, radiation therapy.

<sup>1</sup>Note: the patient's target lesion is a lymph node, which reduced in size to less than 10mm, which is a complete response based on RECIST1.1 criteria.

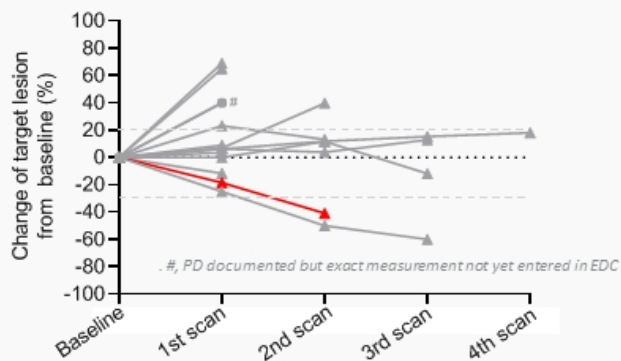


## Patient Profile #2: 77-Year-Old Male with HNSCC and Unconfirmed Partial Response (Dose Level 2 IV-IV)

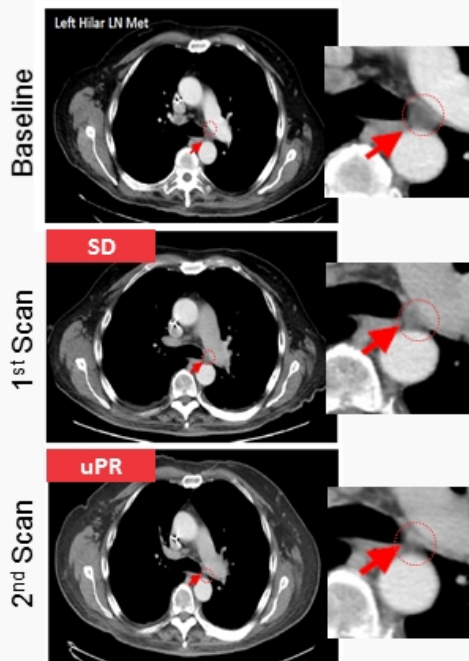
**Prior treatments:** 3 prior lines of therapy  
 Cisplatin + XRT ► Carboplatin/paclitaxel/cetuximab ►  
 Pembrolizumab (21 days since last CPI)

**Results:** Rapid disease stabilization followed by unconfirmed PR  
 20% reduction by C3D1 ► 41% reduction by C5D1

**Status:** Patient remains on study after 94 days



C, cycle; CPI, checkpoint inhibitor; D, day; FU, fluorouracil; XRT, radiation therapy.





## Patient Profile #3: 69-Year-Old Male With HNSCC With Progression, Then Stable Disease (Dose Level 2 IV-IV)

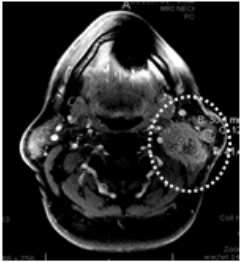
**Prior treatments:** 2 prior lines of therapy

*Durvalumab/monalizumab/cetuximab* ► *Pembrolizumab/carboplatin/5-FU (Keynote-048; 42 days since last CPI)*

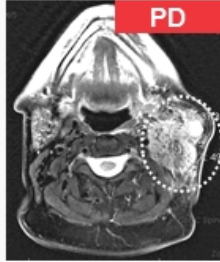
**Results:** PD at first scan followed by disease stabilization

**Status:** Patient is currently on study after 91 days

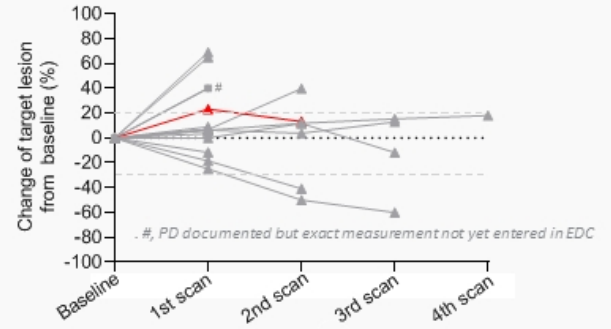
Baseline



1<sup>st</sup> Scan



2<sup>nd</sup> Scan



C, cycle; CPI, checkpoint inhibitor; D, day; FU, fluorouracil; XRT, radiation therapy.

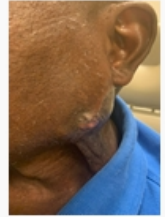
# Patient Profile #4: 68-Year-Old Male With HNSCC With Stable Disease in Combination With Pembrolizumab (Dose Level 2 IV-IV)



**Prior treatments:** 3 prior lines of therapy  
*Pembrolizumab/carboplatin/5-FU ▶ Cetuximab ▶ Pembrolizumab/carboplatin (POD on treatment 38 days since last CPI)*

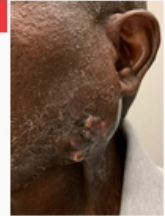
**Results:** Potential target lesion response in combination with pembrolizumab after progression on 2 prior rounds of pembrolizumab

**Status:** Patient is currently on drug after 140 days



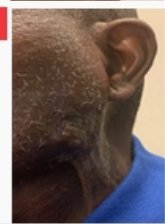
**SD**

Following clinical progression, pembrolizumab was added off protocol

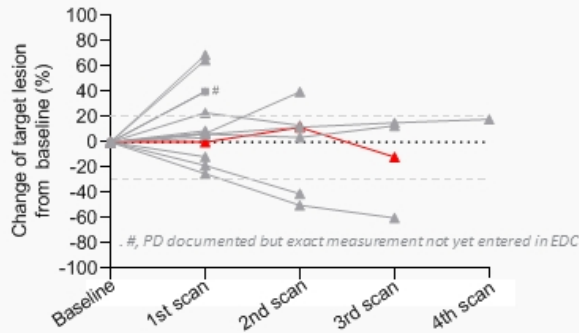


**SD**

Clinical improvement



## Baseline



C, cycle; CPI, checkpoint inhibitor; D, day; FU, fluorouracil; XRT, radiation therapy.

Note: the patient's last day on the trial for response and mPFS attributed to HB-201 is the day prior to the addition of pembrolizumab. SD=Stable Disease via RECIST 1.1

## Initial Phase 1 Cohorts: Promising Interim Data

- Favorable tolerability
- Shows evidence of efficacy in a heavily pretreated patients with HPV16+ cancers
  - **18% unconfirmed response rate** and **73% disease control rate** in 11 evaluable HNSCC patients
    - 1 patient with an unconfirmed complete response
    - 1 patient with an unconfirmed partial response
    - 6 patients with stable disease
  - Median **PFS of 72 days** (and ongoing) for evaluable HNSCC at least third-line patients who all progressed on prior PD1 inhibitors (N=11); compares favorably with nivolumab's Phase 3 mPFS of 60 days in second-line HNSCC

## Phase 1 Cohorts with replicating two-vector therapy of HB-201/HB-202

- First patient dosed in October 2020
- Data expected in mid-2021

## Phase 2

- Further exploration of HB-201 and HB-201/HB-202 at recommended Phase 2 dose
- Explore combinations with PD1 inhibitor

