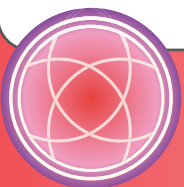


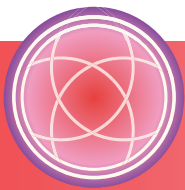
Clinical study	PI (Institution)	Disease area	Target enrollment	NCT number and study objectives
<p><b>Hookipa Pharma Target HPV<sup>1</sup></b></p> <p>A randomized phase I/II trial of TheraT<sup>®</sup> vectors expressing HPV16 specific antigens in combination with neoadjuvant chemotherapy followed by transoral robotic surgery or risk/response stratified chemoradiotherapy for locoregional HPV16+ oropharyngeal cancer</p>	<p>Ari Rosenberg, MD (University of Chicago)</p>	<p><b>OPSCC</b></p>	<p>60 patients/ 600 samples</p>	<p><b>NCT05108870</b></p> <p><b>Primary:</b></p> <p>Phase 1: Safety/tolerability and recommended phase 2 dose of HB-200 with chemotherapy</p> <p>Phase 2: Deep response rate as assessed by tumor shrinkage according to RECIST v1.1</p> <p><b>Secondary:</b></p> <ul style="list-style-type: none"> <li>a) <b>Correlation between plasma HPV-DNA and tumor HPV-DNA</b></li> <li>b) <b>Changes in plasma HPV-DNA</b> during study treatment with HB-201 and alternating HB201/202 combined with chemotherapy</li> <li>c) Pathologic response in patients undergoing transoral robotic surgery</li> <li>d) PFS</li> <li>e) OS</li> <li>f) Locoregional control</li> </ul>
<p><b>Optima 2B<sup>2</sup></b></p> <p>Pilot study of induction chemotherapy followed by risk and response-stratified treatment for locoregional HPV associated oropharyngeal cancer</p>	<p>Nishant Agrawal, MD Ari Rosenberg, MD (University of Chicago)</p>	<p><b>OPSCC</b></p>	<p>47 patients/ 423 samples</p>	<p><b>NCT04572100</b></p> <p><b>Primary:</b></p> <ul style="list-style-type: none"> <li>a) <b>Feasibility of collection of serial HPV-DNA blood samples</b> in OPSCC patients undergoing treatment</li> <li>b) Evaluate <b>relationship between HPV-DNA</b> found in patient's blood and patient <b>response to chemotherapy</b></li> </ul> <p><b>Secondary:</b></p> <ul style="list-style-type: none"> <li>a) <b>Changes in blood containing HPV-DNA during response-based therapy</b></li> <li>b) Side effects of cisplatin-based chemotherapy treatment</li> <li>c) Tumor response among patients undergoing transoral robotic surgery</li> <li>d) Time to disease recurrence</li> <li>e) OS</li> <li>f) Locoregional control</li> <li>g) Distant control</li> </ul>
<p><b>JHU HPV-SEQ IIS<sup>3</sup></b></p> <p>A novel pilot study of ctHPV DNA as a dynamic, quantitative biomarker of treatment response in OPSCC</p>	<p>Tanguy Seiwert, MD (Johns Hopkins University)</p>	<p><b>OPSCC</b></p>	<p>17 patients/ 125 samples</p>	<p><b>Primary:</b></p> <p>To characterize <b>ctHPV DNA kinetics during definitive non-surgical management</b> (induction chemotherapy followed by radiation therapy) of HPV-associated OPSCC patients undergoing routine standard of care treatment</p> <p><b>Secondary:</b></p> <ul style="list-style-type: none"> <li>a) To identify a <b>post-induction chemotherapy ctHPV DNA percentage clearance</b> threshold that predicts for accelerated complete clearance of ctHPV DNA during chemoradiation in HPV-related oropharyngeal cancer patients</li> <li>b) To <b>correlate ctHPV DNA changes</b> with standard of care <b>radiographic assessment</b> of treatment response</li> <li>c) To investigate relationship between <b>ctHPV DNA clearance</b> at the end of treatment and 2-year PFS for HPV-related oropharyngeal cancer</li> </ul>



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Clinical study	PI (Institution)	Disease area	Target enrollment	NCT number and study objectives
<p><b>ECOG-ACRIN HPV-SEQ<sup>4,5</sup></b></p> <p>A randomized phase III study of immune checkpoint inhibition with chemotherapy in treatment-naïve metastatic anal cancer patients</p>	<p>Cathy Eng, MD (Vanderbilt University)</p>	<p><b>Anal</b></p>	<p>200 patients/ 1,000 samples</p>	<p><b>NCT04444921</b></p> <p><b>Primary:</b></p> <p>To demonstrate that anti-PD-1 therapy (Nivolumab) + carboplatin/weekly paclitaxel results in improved PFS vs systemic therapy alone</p> <p><b>Secondary:</b></p> <p>a) To demonstrate that experimental arm results in improved OS and ORR using RECIST v1.1 vs systemic therapy alone</p> <p>b) To evaluate toxicity of the two regimens</p> <p>c) To evaluate the role of <b>tumor-derived cell-free ctDNA in monitoring treatment response</b></p>
<p><b>JHU Cervical Cancer IIS<sup>3</sup></b></p> <p>A novel pilot study of ctHPV DNA as a dynamic, quantitative biomarker of treatment response in cervical cancer</p>	<p>Akila Viswanathan, MD MPH (Johns Hopkins University)</p>	<p><b>Cervical</b></p>	<p>30 patients/ 300 samples</p>	<p><b>Primary:</b></p> <p>To characterize <b>ctHPV DNA kinetics</b> during definitive non-surgical management</p> <p><b>Secondary:</b></p> <p>a) To identify <b>ctHPV DNA percentage clearance threshold</b> after external beam radiation therapy with concurrent chemotherapy that predicts for complete clearance of ctHPV DNA during the brachytherapy course in HPV-related cervical cancer patients</p> <p>b) To <b>correlate ctHPV DNA changes</b> with standard of care <b>radiographic assessment</b> of treatment response after external beam radiation therapy and at 3 months after completion of all therapy</p> <p>c) To investigate relationship between <b>ctHPV DNA clearance</b> at the end of treatment and 2-year PFS</p>



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ct, circulating tumor; ECOG-ACRIN, Eastern Cooperative Oncology Group-the American College of Radiology Imaging Network; HPV, human papillomavirus; IIS, investigator-initiated study; NCT, national clinical trial; OPSCC, oropharyngeal squamous cell carcinoma; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein-1; PFS, progression-free survival; PI, principal investigator; RECIST, Response Evaluation Criteria in Solid Tumors; SEQ, sequencing.

\*Patient enrollment initiated in Feb 2024.

**References:** 1. ClinicalTrials.gov identifier: NCT05108870. Updated August 29, 2023. Accessed April 30, 2024. Available at: <https://clinicaltrials.gov/study/NCT05108870>. 2. ClinicalTrials.gov identifier: NCT04572100. Updated July 7, 2023. Accessed April 30, 2024. Available at: <https://clinicaltrials.gov/study/NCT04572100>. 3. JHU Approved IRB protocol document #IRB00289711. 4. ClinicalTrials.gov identifier: NCT04444921. Updated April 30, 2024. Accessed April 30, 2024. Available at: <https://clinicaltrials.gov/study/NCT04444921>. 5. Roth MT et al. J Clin Onc. 2021;39(supplement\_15):TPS3614.

**Sysmex Inostics, Inc.** 1812 Ashland Ave, Suite 500, Baltimore, MD 21205, USA  
 info@sysmex-inostics.com  
[www.sysmex-inostics.com](https://www.sysmex-inostics.com)

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