Clinical trials and investigator initiated studies using HPV-SEQ

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Clinical study	PI (Institution)	Disease area	Target enrollment	NCT number and study objectives
Hookipa Pharma Target HPV[1] A randomized phase I/II trial of TheraT® 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	Ari Rosenberg, MD (University of Chicago)	**OPSCC**	60 patients/ 600 samples	**NCT05108870** **Primary:** Phase 1: Safety/tolerability and recommended phase 2 dose of HB-200 with chemotherapy Phase 2: Deep response rate as assessed by tumor shrinkage according to RECIST v1.1 **Secondary:** a) **Correlation between plasma HPV-DNA and tumor HPV-DNA** b) **Changes in plasma HPV-DNA** during study treatment with HB-201 and alternating HB201/202 combined with chemotherapy c) Pathologic response in patients undergoing transoral robotic surgery d) PFS e) OS f) Locoregional control
Optima 2B[2] Pilot study of induction chemotherapy followed by risk and response-stratified treatment for locoregional HPV associated oropharyngeal cancer	Nishant Agrawal, MD Ari Rosenberg, MD (University of Chicago)	**OPSCC**	47 patients/ 423 samples	**NCT04572100** **Primary:** a) **Feasibility of collection of serial HPV-DNA blood samples** in OPSCC patients undergoing treatment b) Evaluate **relationship between HPV-DNA** found in patient's blood and patient **response to chemotherapy** **Secondary:** a) **Changes in blood containing HPV-DNA during response-based therapy** b) Side effects of cisplatin-based chemotherapy treatment c) Tumor response among patients undergoing transoral robotic surgery d) Time to disease recurrence e) OS f) Locoregional control g) Distant control
JHU HPV-SEQ IIS[3] A novel pilot study of ctHPV DNA as a dynamic, quantitative biomarker of treatment response in OPSCC	Tanguy Seiwert, MD (Johns Hopkins University)	**OPSCC**	17 patients/ 125 samples	**Primary:** To characterize **ctHPV DNA kinetics during definitive non-surgical management** (induction chemotherapy followed by radiation therapy) of HPV-associated OPSCC patients undergoing routine standard of care treatment **Secondary:** a) To identify a **post-induction chemotherapy ctHPV DNA percentage clearance** threshold that predicts for accelerated complete clearance of ctHPV DNA during chemoradiation in HPV-related oropharyngeal cancer patients b) To **correlate ctHPV DNA changes** with standard of care **radiographic assessment** of treatment response c) To investigate relationship between **ctHPV DNA clearance** at the end of treatment and 2-year PFS for HPV-related oropharyngeal cancer

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CONT'D >

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

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ct, circulating tumor; ECOG-ACRYN, 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.
[a]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 el. J Clin Onc. 2021;39(supplement_15):TPS3614.

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