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[1,2] 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**	98 patients	**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
UChicago HPV-SEQ IIS[3-5] Pilot study of induction chemotherapy followed by risk and response-stratified treatment for locoregional HPV associated oropharyngeal cancer	Ari Rosenberg, MD (University of Chicago)	**OPSCC**	50 patients	**NCT04572100, NCT03107182** **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
Optima 2[6,7] A Phase II trial of nivolumab/nab-paclitaxel/carboplatin induction chemotherapy followed by response-stratified locoregional therapy for patients with locoregionally advanced HPV-related oropharyngeal cancer-the Optima 2 Trial	Ari Rosenberg, MD (University of Chicago)	**OPSCC**	76 patients	
JHU HPV-SEQ IIS[8] 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	**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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Clinical study	PI (Institution)	Disease area	Target enrollment	NCT number and study objectives
ECOG-ACRIN HPV-SEQ[9,10] A randomized phase III study of immune checkpoint inhibition with chemotherapy in treatment-naive metastatic anal cancer patients	Cathy Eng, MD (Vanderbilt University)	**Anal**	250 patients	**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[8] 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	**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 May 9, 2024. Accessed September 12, 2024. Available at: https://clinicaltrials.gov/study/NCT05108870. 2. Rosenberg AJ et al. *J Clin Onc.* 2024;42(supplement_16):6017. 3. ClinicalTrials.gov identifier: NCT04572100. Updated July 7, 2023. Accessed September 12, 2024. Available at: https://clinicaltrials.gov/study/NCT04572100. 4. Rosenberg AJ et al. *Annals of Oncol.* 2023 Oct;34(supplement_2):S568. 5. Rosenberg AJ, et al. *BMC cancer.* 2022 Dec;22:17. 6. ClinicalTrials.gov identifier: NCT03107182. Updated August 28, 2023. Accessed September 12, 2024. Available at: https://clinicaltrials.gov/study/NCT03107182. 7. Rosenberg AJ et al. *JAMA Oncol.* 2024;10(7):923-931. 8. JHU Approved IRB protocol document #IRB00289711. 9. ClinicalTrials.gov identifier: NCT04444921. Updated August 29, 2024. Accessed September 12, 2024. Available at: https://clinicaltrials.gov/study/NCT04444921. 10. Roth MT et al. *J Clin Onc.* 2021;39(supplement_15):TPS3614.

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