Head & Neck POD Portfolio						
Protocol	**Status**	**Trial Name**	**PI/SC**	**Setting**	**Trial Details**	**Slots**
NBTXR3-1100	OPEN	A Phase I Study of NBTXR3 Activated By Radiotherapy for Patients with Advanced Cancers Treated With an Anti-PD1 Therapy	Shen/Stephanie Corbett	2nd Line +	**Key Eligibility:** Patients with mets to lung or superficial soft tissues - pretreatment with PD1 acceptable. Inoperable NSCLC, melanoma, HCC, RCC, urothelial cancer, cervical cancer, TNBC metastasized to lung, soft tissues or liver amenable to injection/irradiation.	Please contact Stephanie for Availability
LCCC 2047	OPEN	A Phase II Trial of Induction and Maintenance Pembrolizumab and Olaparib in Locally-Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)	Sheth/Stephanie	Definitive Chemoradiation	**Key Eligibility:** stage III-IVB oral cavity squamous cell carcinoma (SCC), p16-negative oropharyngeal SCC, stage III-IVB hypopharyngeal SCC, stage III- IVB laryngeal SCC -OR- HPV-associated oropharyngeal SCC - No prior curative attempts for this cancer - No metastatic disease	
NANORAY312	OPEN	A Phase 3 (Pivotal Stage) Study of NBTXR3 Activated by Investigator s Choice of Radiotherapy Alone or Radiotherapy in Combination with Cetuximab for Platinum-based Chemotherapy-Ineligible Elderly Patients with Locally Advanced Head & Neck Squamous Cell Carcinoma	Shen/Stephanie Corbett	1st line	**Key Eligibility:** Patients 65 and older with LA-HNSCC who are ineligible to receive platinum-based chemotherapy. T3-T4 SCC of the oral cavity, oropharynx, hypopharynx, or supraglottic larynx; at least one measurable tumor, can inject LN along with primary tumor	
NRG-HN006	**TEMPORARILY CLOSED**	Randomized Phase II/III Trial of Sentinel Lymph Node Biopsy Versus Elective Neck Dissection for Early-Stage Oral Cavity Cancer	Hackman/Dawniqua Collier	***Surgery***	**Key Eligibility:** Pathologically proven diagnosis of squamous cell carcinoma of the oral cavity, including the oral (mobile) tongue, floor of mouth (FOM), mucosal lip, buccal mucosa, lower alveolar ridge, upper alveolar ridge, retromolar gingiva (retromolar trigone; RMT), or hard palate Patient must be a candidate for surgical intervention with sentinel lymph node (SLN) biopsy and potential completion neck dissection (CND) or elective neck dissection (END)	
NCI-10553	**OPEN**	A Phase 2 Study of Darolutamide in Combination with Leuprolide Acetate in Hormone-Therapy Naïve Recurrent and/or Metastatic Androgen Receptor (AR) Positive Salivary Gland Cancer	Patel/Stephanie Corbett	1st line ADT	**Key Eligibility:** - salivary gland cancer that is recurrent/metastatic or unresectable/locally advanced, with AR expression detected by IHC on a CLIA-approved assay. -No prior AR-targeted therapy, except for AR-targeted therapy administered in the neoadjuvant and/or adjuvant setting and with disease recurrence more than 6 months since treatment completion.	Sites should contact the study contact if they have potential pt and will add the patient to the waitlist.

					-ECOG performance status ≤2	
A092105	**OPEN**	A Randomized Phase 2 Study Of Nivolumab and Ipilimumab With Or Without Cabozantinib in Patients with Advanced Nasopharyngeal Carcinoma That Have Progressed After Platinum Treatment and Immunotherapy	Sheth/Dawniqua Collier	2nd Line +	**Key Eligibility:** - histologically documented nasopharyngeal carcinoma (WHO) classification) and regardless of association with Epstein-Barr virus (EBV) and/or human papillomavirus (HPV). - Recurrent, metastatic and incurable disease treated with platinum-gemcitabine and prior PD-1/L1 blockade (as first or second-line therapy) where immunotherapy was part of the most recent prior line of therapy - ECOG Performance Status 0-2	-
61186372HNC2002	**Open**	A Phase 1b/2, Open-label Study of Amivantamab Monotherapy and Amivantamab in Addition to Standard of Care Therapeutic Agents in Participants with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma	Sheth/Rebecca Rambharose	2nd Line +	Key Eligibility: - Have histologically or cytologically confirmed R/M HNSCC that is considered incurable by local therapies. Have measurable disease according to RECIST v1.1 - Have an ECOG performance status of 0 to 1	Cohort 1 Ami Monotherapy Cohort 2 Ami + Pembro Cohort 4 Ami Monotherapy (HPV+)
LCCC 1835	**OPEN**	Circulating Tumor DNA (ctDNA) in Locally Advanced Head and Neck Squamous Cell Carcinoma	Sheth/Adrianna Warner		Key Eligibility: • Histologically confirmed squamous cell carcinoma of the head and neck, including the following subtypes: oral cavity, oropharynx, larynx • Must be planning to undergo gross total resection of the primary tumor with curative intent at UNC-CH hospital	

LCCC 2255	**NEW**	Neoadjuvant XL092 and cemiplimab prior to surgery in BRAF V600E-wildtype anaplastic thyroid cancer: a phase 1B study	Sheth			
INBRX106-01-201	**NEW**	INBRX-106 in Combination With Pembrolizumab in First-line PD-L1	Sheth/Dawniqua Collier	1st line		
RPL-003-19	**NEW**	An Open-Label, Multicenter, Phase 1B/2 Study of RP1 in Solid Organ and Hematopoietic Cell Transplant Recipients With Advanced Cutaneous Malignancies [ARTACUS]	Sheth/Dawniqua Collier			
MCLA-158-CL-02	**NEW**	A phase 3 open-label, randomized, controlled study to evaluate the efficacy and safety of petosemtamab compared with investigator's choice monotherapy treatment in previously treated patients with incurable, metastatic/recurrent head and neck squamous cell carcinoma	Sheth/ Stephanie Corbett			
RRP-331	**NEW**	RRP-331- A phase 3, randomized, placebo controlled, blinded trial of INO-3107 with electroporation (EP) in subjects with HPV-6 and/or HPV-11-associated recurrent respiratory papillomatosis (RRP)	Sheth/Dawniqua Collier			
EA3231	**NEW**	A Randomized Phase III Study of BRAF-Targeted Therapy vs Cabozantinib in RAI-Refractory Differentiated Thyroid Cancer with BRAF V600Em	Sheth/ Stephanie Collier			
1463-001	**NEW**	A Study to Test BI 765179 Alone and in Combination With Ezabenlimab in Patients With Advanced Cancer	Trivedi/ Jasmine Jordan			

Studies Outside of Head & Neck						
TAPUR	OPEN	Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a Tumor Gene in People With Advanced Stage Cancer (TAPUR)	**Patel/Elizabeth Schwabe**	Biomarker Cohorts: - atezolizumab + talazoparib: germline or somatic BRCA1/2; PALB2, ATM, ATR, CHEK2, FANCA, RAD51C, NBN, MLH1, MRE11A, CDK12 - futibatinib: FGFR1 or FGFR3 fusion, rearrangement, or mutation - larotrectinib: NTRK amplification - nivolumab/ipilimumab: MSI high; MLH1, MSH2 or 6, PMS2, EPCAM mutations, POLD1, POLE, DDR mutations - pembrolizumab: POLE1, POLD1 mutations - regorafenib: KIT or BRAF mutations or amplification - talazoparib: CHEK2, PALB2 mutation - tucatinib + trastuzumab/pertuzumab: ERBB2 amplification or overexpression	**Catch all advanced solid tumors** - treatment assigned based on molecular profiling. Patient (age ≥ 12 years*) with a histologically-proven locally advanced or metastatic solid tumor, multiple myeloma or B cell non-Hodgkin lymphoma who is no longer benefitting from standard anti-cancer treatment or for whom, in the opinion of the treating physician, no such treatment is available or indicated.	Open cohort info: https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/research-data/documents/Public-facing_Cohort_Report.pdf
CT-0508-101	OPEN	A Phase 1, First in Human Study of Adenovirally Transduced Autologous Macrophages Engineered to Contain an Anti-HER2 Chimeric Antigen Receptor in Subjects with HER2 Overexpressing Solid Tumors.	**Abdou/Catherine Cheng**	locally advanced (unresectable) or metastatic solid tumors overexpressing HER2, who have failed available therapies including the approved anti-HER2 therapies	**Key Eligibility:** fresh biopsy showing HER2 positive	
PBI-MST-01 (Presage)	SUSPENDEND (awaiting addition of new cohort)	A Phase 0 Master Protocol Using the CIVO® Platform to Evaluate Intratumoral Microdoses of Anti-Cancer Therapies in Patients With Solid Tumors	**Sheth/Olivia Gorman**	Assessing localized PD of anti-cancer therapies within the TME when administered intratumorally in microdose quantities via the CIVO device in patients with surface accessible solid tumors for which there is a scheduled surgical intervention.	**Assessing localized PD of anti-cancer therapies** within the TME when administered intratumorally in microdose quantities via the **CIVO device in patients with surface accessible solid tumors for which there is a scheduled surgical intervention. At least one lesion (primary tumor, recurrent tumor, or effaced metastatic lymph node) ≥ 2 cm in the shortest diameter that is surface accessible for CIVO injection** that may be guided by ultrasound if appropriate and for which there is a planned surgical intervention.	Enrollment suspended until new cohort opens. Date TBD.

NX-1607-101	OPEN	A Phase 1a, Dose Escalation, Safety and Tolerability Study of NX-1607, a Casitas B-lineage lymphoma proto-oncogene (CBL-B) inhibitor, in Adults with Advanced Malignancies, with Phase 1b Expansion in Select Tumor Types	**Weiss/Elizabeth Schwabe**	Must have metastatic, unresectable disease, not candidates for SOC. Cancer types: platinumresistant epithelial ovarian cancer (EOC), gastric cancer, squamous cell carcinoma of the head and neck (HNSCC), recurrent and either metastatic or unresectable melanoma, non-small cell lung cancer (NSCLC), metastatic castration-resistant prostate cancer (mCRPC), malignant pleural mesothelioma (MPM), triple-negative breast cancer (TNBC), locally advanced or metastatic urothelial cancer, cervical cancer, microsatellite stable colorectal cancer (MSS CRC), and diffuse large B-cell lymphoma (DLBCL) including patients with Richter transformation (DLBCL-RT).	***Must have metastatic, unresectable disease, not candidates for SOC. Cancer types:*** *platinum-resistant epithelial ovarian cancer (**EOC**), gastric cancer, squamous cell carcinoma of the head and neck (**HNSCC**), recurrent and either metastatic or unresectable **melanoma**, non-small cell lung cancer (**NSCLC**), metastatic castration-resistant prostate cancer (**mCRPC**), malignant pleural mesothelioma (**MPM**), triple-negative breast cancer (**TNBC**), locally advanced or metastatic **urothelial cancer, cervical** cancer, microsatellite stable colorectal cancer (**MSS CRC**), and diffuse large B-cell lymphoma (**DLBCL**) including patients with Richter transformation (**DLBCL-RT**).*	Ask Elizabeth for availability

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