GU POD PORTFOLIO GRID					
	NMIBC	MIBC – Neoadjuvant			
		Cisplatin Eligible	Cisplatin Ineligible	Bladder Sparing	Adjuvant
Carcinoma Urothelial	**iGEMBRO (A031803)** Phase 2 of intravesical gemcitabine + pembrolizumab in BCG-unresponsive NMIBC *(SC: Maxine Maxwell; PI: Milowsky)* Eligibility: - BCG-unresponsive NMIBC - Unfit or refuse radical cystectomy - Received adequate BCG and w/in 12 months of last BCG instillation - Mixed histology allowed; no pure non-UC				**MODERN / A032103** An Integrated Phase 2/3 and Phase 3 Trial of MRD-Based Optimization of Adjuvant Therapy in Urothelial Cancer *(SC: Robert Morton; PI: Milowsky)* Eligibility: - **Histologically confirmed muscle-invasive urothelial carcinoma of the bladder.** Variant histology, including neuroendocrine differentiation, **is allowed if urothelial cancer is predominant histology** (any amount of squamous differentiation is allowed provided the tumor is not a pure squamous cell cancer). - Patient must have had radical cystectomy and lymph node dissection **≥ 3 weeks, but ≤ 12 weeks prior to pre-registration. Patients who have had a partial cystectomy** as definitive therapy **are not eligible.** - **No gross cancer at the surgical margins.** Microscopic invasive urothelial carcinoma at the surgical margins (i.e., "positive margins") are allowed. Carcinoma in situ (CIS) at margins is considered negative margins.

Carcinoma Urothelial					- Have undergone a radical cystectomy with pathological evidence of **urothelial carcinoma of the bladder at high risk of recurrence** as described in one of the two scenarios below (i or ii): - **Available tumor tissue for central Signatera testing to be submitted after pre-registration.**
	Metastatic				
	1st Line		2nd Line		3rd + Line
	Opening Soon **RC48G001** A Phase 2 Multi-Cohort, Open-Label, Multi-Center Clinical Study Evaluating the Efficacy and Safety of Disitamab Vedotin (RC48-ADC) Alone or in Combination with Pembrolizumab in Subjects with Locally-Advanced Unresectable or Metastatic Urothelial Carcinoma That Expresses HER2 *(SC: Maxine Maxwell; PI: Milowsky)* Eligibility:		**AT148007 (ASPEN)** A study of ALX148 with enfortumab vedotin for subjects with urothelial carcinoma *(SC: Robert Morton; PI: Milowsky)* Eligibility: - Must have received prior CPI in the locally advanced or metastatic setting - Must have had progression or recurrence of urothelial cancer during or following receipt of most recent therapy - ECOG 0-1 - Archival tissue required for dose escalation cohorts **LOXO-FG3-22001** A Phase 1 a/b study of LOXO-435 in advanced solid tumor malignancies with FGFR3 alterations *(SC: Jill Holmes; PI: Milowsky)* Eligibility: - Histologic dx of locally advanced or metastatic solid tumor malignancy (except CNS primary malignancy) w/ an *FGFR3* pathway alteration on molecular testing in tumor or blood sample that is deemed as actionable (as define by specific cohort)		**FX-909-CLIN-002** A Phase 1, First-in-Human, Dose-Escalation and Expansion Study of FX-909 in Patients with Advanced Solid Malignancies, Including Advanced Urothelial Carcinoma (SC: *Robert Morton; PI: Milowsky)* Eligibility: - ECOG 0-2 - Part A (dose escalation): histologically/cytologically diagnosed, locally advanced (unresectable) or metastatic solid malignancies that have progressed after all available standard therapy for the specific tumor type, or for which no standard therapy exists. Patients for whom standard therapies are intolerable or considered inappropriate by the Investigator are eligible. - Part B (expansion): Histologically/cytologically

Carcinoma Urothelial		- Measurable or non-measurable disease as defined by RECIST v1.1 - Life expectancy of >12 weeks - Have adequate archival tissue sample available or undergo a screening bx (pts w/ inadequate tissue sample availability may reach out to medical monitor) - ECOG = 0-1 - Patients have received all SOC for which the patient was deemed to be an appropriate candidate by the treating investigator; or the patient is refusing the remaining most appropriate SOC TX; or there is no SOC TX available for the disease. - Must be able to swallow oral tablets. ACR-368-201 A Phase IB/2 basket study of ACR-368 as monotherapy and in combination with gemcitabine in adult subjects with platinum-resistant ovarian carcinoma, endometrial adenocarcinoma, and urothelial carcinoma based on acrivon OncoSignature® status *(SC: Robert Morton; PI: Milowsky)* Eligibility: - Histologically confirmed, locally advanced or metastatic cancer that has progressed during or after at least 1 prior TX - Subject must be willing to provide tissue from a newly obtained tumor biopsy (archival tissue block or at least 20 unstained slides, if available - Subject must have stabilized or recovered (grade 1 or baseline) from all prior TX-related toxicities (w/ exceptions) - Measurable disease per RECIST v1.1 - ECOG = 0-1 - Life expectancy of greater than 3 months - No systemic or radiation therapy within 2 weeks prior to the first dose of study drug.	diagnosed, locally advanced (unresectable) or metastatic urothelial carcinoma with defined genetic alterations defined below (PPARG, A PPARG fusion, an activating mutation in PPARG, an activating mutation in RXRA, mutations or fusions of FGFR3) - Archival tissue that is no more than 30 months old at the time of screening or a fresh bx is required. - No prior anti-cancer therapy within 2 weeks prior to C1D1. - AEs that have not resolved from prior therapy to baseline or grade 1 (except alopecia, hearing loss, vitiligo, edocrinopathy managed with replacement therapy, and grade <2 neuropathy. - No major surgery within 4 weeks. Opening Soon RC48G001 A Phase 2 Multi-Cohort, Open-Label, Multi-Center Clinical Study Evaluating the Efficacy and Safety of Disitamab Vedotin (RC48-ADC) Alone or in Combination with Pembrolizumab in Subjects with Locally-Advanced Unresectable or Metastatic Urothelial Carcinoma That Expresses HER2 *(SC: Maxine Maxwell; PI: Milowsky)* Eligibility:

Carcinoma Urothelial		- Tumor Type-Specific Inclusion Criteria Opening Soon RC48G001 A Phase 2 Multi-Cohort, Open-Label, Multi-Center Clinical Study Evaluating the Efficacy and Safety of Disitamab Vedotin (RC48-ADC) Alone or in Combination with Pembrolizumab in Subjects with Locally-Advanced Unresectable or Metastatic Urothelial Carcinoma That Expresses HER2 *(SC: Maxine Maxwell; PI: Milowsky)* Eligibility:	

Carcinoma Urothelial			

	LOCALIZED	BIOCHEMICAL RECURRENCE	METASTATIC		
			1ST Line	2nd Line	2nd / 3rd Line
Prostate	**Suspended** **LCCC1917 (RadOnc)** Steering Dose Inhomogeneity of Stereotactic Body Radiotherapy Towards the Lesion Defined by 68Ga-HBED-CC PSMA-PET/mpMRI in Low and **Intermediate Risk Localized Prostate Cancer** Patients *(SC: Flora Danquah PI: Dr. Repka)* Eligibility: - Low or favorable intermediate risk, based on the NCCN criteria, w/ bone scan - ECOG 0-2 - Subject must speak English - No contraindications for MRI - No inflammatory bowel disease - No previous TURP or surgery of the prostate + PROTEUS sub-study run through Urology			**PRESERVE-006** Randomized Study of ONC-392 plus Lutetium Lu 177 Vipivotide Tetraxetan in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) who Progressed on Androgen Receptor (AR) Pathway Inhibition *(SC: Jill Holmes; PI: Whang)* Eligibility: This study will enroll participants who have castration resistant prostate cancer and have disease progression after androgen receptor targeting agents, with or without prior chemotherapy. It will be determined if the PT will receive either ONC-392 plus PLUVICTO® vs. PLUVICTO® alone. The ratio will be 2 to 1, with twice as many subjects in the arm receiving ONC-392 plus PLUVICTO®.	**DORA (c16-174)** Phase 3 Trial of Docetaxel vs. Docetaxel and Radium-223 for mCRPC *(SC: Doug Whelan; PI: Whang)* Eligibility: - Documented proof of progressive mCRPC - Presence of 2 or more bone lesions defined by nuclear scan - Serum testosterone level below 50 ng/dL - No prior prostate directed chemotherapy in castrate resistant setting **OPENING SOON** **20230238 (AMG 509)** *A Phase 1b, Open-label, Multicenter Study Evaluating the Safety, Tolerability, and Efficacy of Xaluritamig in Subjects With High-risk Biochemical Recurrence of Nonmetastatic Castration-sensitive Prostate Cancer After Definitive Therapy (AMG 509)* *(SC: John/Jill; PI: Whang)* Eligibility: -
Renal	**LOCALIZED**	**ADJUVANT**	**METASTATIC**		
			1ST Line	**2nd Line**	**2nd / 3rd Line**
			A031704 (PDIGREE) **CLOSED TO ACCURAL**	**A031801 (RADICAL)** Cabo +/- Radium-223 in mRCC with bone mets	

Renal			Ipi/nivo followed by nivolumab vs. nivo/cabo in patients with non-CR/non-PD *(SC: Jill Holmes/Jessica Greenwood; PI: Rose)* Eligibility: - Renal cell carcinoma (including clear cell components, sarcomatoid or rhabdoid features, any metastatic disease) - Must have intermediate or poor risk patient per IMDC criteria. - CNS disease permitted, if stable and not otherwise causing symptoms or needing active treatment. - No prior TX w/ PD-1, PD-L1, or CTLA-4 targeting agents, or any other drug or antibody specific targeting T-cell co-stimulation or checkpoint pathways. **NRG-GU012 (SAMURI)** Randomized Phase II Stereotactic Ablative Radiation Therapy (SABR)	*(SC: Jill Holmes; PI: Rose)* Eligibility: - Documented histologic if cytologic diagnosis of RCC. - The presence of at least 1 metastatic bone lesion not previously treated. - No prior TX w/ cabozantinib - No major surgery w/in 6 weeks - No brain mets or cranial epidural disease - No concomitat anticoagulation	

Renal			for Metastatic Unresected Renal Cell Carcinoma (RCC) Receiving Immunotherapy *(SC: Robert Morton; PI: Rose)* Eligibility: - histologic if cytologic diagnosis of RCC. - Node-positive unresectable (TxN1Mx) or metastatic (TxNxM1) based on Physical Exam, CT/MRI within 45 days prior to registration. - Patients must have IMDC intermediate (1-2 factors) or poor risk disease (>3 factors) - Candidate for SOC TX with either IO-IO or IO-VEGF combination regimen. - Primary renal tumor measuring 8cm or less in anterior to posterior dimension only on axial imaging.		

Germ Cell	**LOCALIZED**	**ADJUVANT**	**METASTATIC**		
			1st Line	**2nd Line**	**2nd / 3rd Line**
				LCCC 2048 *(CT pod)* Phase II Study of the Administration of T Lymphocytes Expressing the CD30 Chimeric Antigen Receptor (CAR)	

Germ Cell				for Patients with CD30+ Nonseminomatous Germ Cell Tumors (NSGCT) *(SC: Caroline Babinec/ Megan Gonzalez/ (CT pod); PI: Dr. Milowsky)* ***Agent***: CD30-directed CAR-T Eligibility: - Progressive or recurrent NSGCT after at least one prior line of therapy - Confirmed expression of CD30; archival tissue available or willing to undergo biopsy	
	LOCALIZED	ADJUVANT	METASTATIC		
			1ST Line	2nd Line	2nd / 3rd Line
Rare Tumor – All Sites			**A031702 (ICONIC)** Phase II study of cabozantinib in combination with nivolumab and ipilimumab in rare genitourinary tumors *(SC: Catherine Griffin; PI: Dr. Rose)* Eligibility: - Metastatic disease - Archival/Fresh tissue for central review required - Up to 2 systemic anti-cancer TXs or TX naïve - No active brain mets or epidural disease - Registration to the following cohorts is open: renal collecting duct, bladder plasmacytoid, sarcomatoid bladder, urethral carcinoma (which allows any	**A031702 (ICONIC)** Phase II study of cabozantinib in combination with nivolumab and ipilimumab in rare genitourinary tumors *(SC: Catherine Griffin; PI: Dr. Rose)* Eligibility: - Metastatic disease - Archival/Fresh tissue for central review required - Up to 2 systemic anti-cancer TXs or TX naïve - No active brain mets or epidural disease - Registration to the following cohorts is open: renal collecting duct, bladder plasmacytoid, sarcomatoid bladder, urethral carcinoma (which allows any histology urothelial, squamous, clear cell, or adenocarcinoma), and Bone only (which allows for any GU histology, except prostate).	

Rare Tumor – All Sites			histology urothelial, squamous, clear cell, or adenocarcinoma), and Bone only (which allows for any GU histology, except prostate).		
Phase I POD					**TAPUR (Phase 1)** Testing the Use of Food and Drug Administration (FDA) Approve Drugs That Target a Special Abnormality in a Tumor Gene in People With Advanced Stage Cancer *(SC: Emmie Cole; PI: Dr. Patel)* **APL-101-01 (Phase 1)** Phase 1 / 2 Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects with Non-Small Cell Lung Cancer with c-Met EXON 14 skip mutations and c-Met Dysregulation Advance Solid Tumors *(SC: Doris Caldwell; PI: Dr. Dees)* *Opening Soon* **NX-1607-101 (Phase 1)** 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 *(SC: TBD; PI: Dr. Weiss)* **9801-CL-0101 (Phase 1)** A Phase 1, Open-Label Study of ASP9801, an Oncolytic Virus, Administered by Intratumoral Injection in Patients with Advanced/Metastatic Solid Tumors *(SC: Emmie Cole; PI: Dr. Sheth)*
TSHS Studies					
Status	**Protocol**	**PI/SC**	**Title**	**Indication**	**TSHS Contact Info**
Open	LCCC 1212	Milowsky/Hannah & Stephanie	Collection of Tissue, Blood, Urine, Hair, and Saliva for Research Related to Patients with Genitourinary Malignancies	All GU	**Study Coordinators:** Hannah_Mabey@med.unc.edu Stephanie_Drotts@med.unc.edu **Scientific Research Manager:**

Open	IRONMAN (C16-170)	Whang/Hannah	Prostate Cancer Outcomes: An International Registry to Improve Outcomes in Men with Advanced Prostate Cancer (IRONMAN)	mHSPC or CRPC	**Julianna_Maccarone@med.unc.edu**
Open	IRIONMAN (C16-170C) Sub study	Whang/Hannah	Clinical Utility of an AI-Enabled PSMA-Targeted Imaging Biomarker in Prostate Cancer (CUETIP), an IRONMAN Registry sub-study	mHSPC or CRPC	
Closed	LCCC 2126	Rose/Stephanie	PRO-VISION: Patient Reported Outcomes-Based Monitoring of VEGF-Inhibitor Side Effects in ONcology	RCC	
Open	Odyssey	Rose/Stephanie	Outcomes Database to Prospectively Assess the Changing Therapy Landscape in Renal Cell Carcinoma (ODYSSEY RCC)	RCC	

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