Version
08/22/2024

Phase 1 POD Current Portfolio						
Protocol	**Status**	**PI/SC**	**MOA**	**Protocol Title**	**Available Cohort's Populations**	**Slots**
849-001 (Mirati)	OPEN	Weiss/Olivia	KRAS inhibition in combination with immune checkpoint inhibitor	A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation	• Phase 1b Cetux in NSCLC or PDAC • Phase 2 Cohort D: Other Tumor Types	
APL-101-01	OPEN	Dees/Elizabeth	Novel, selective small molecule MET inhibitor. MET is a receptor tyrosine kinase that, after binding with its ligand, hepatocyte growth factor, activates a wide range of different cellular signaling pathways, including those involved in proliferation, motility, migration, and invasion.	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	**Non-Small Cell Lung Cancer with c-Met EXON 14 skip mutations and c-Met Dysregulation Advance Solid Tumors.** Cohorts: • A-1 (NSCLC harboring Exon 14 skipping mutations, untreated) • A-2 (NSCLC harboring Exon 14 skipping mutations, previously treated) • C (MET amplification basket tumor types excluding primary CNS tumors) • **C-1 (NSCLC with MET amplification, MET naive),** • D (c-Met-gene fusion basket type) • E (Primary CNS tumors with MET alterations)	Cohort A-1: OPEN Cohort A2: OPEN Cohort B: CLOSED Cohort C: CLOSED Cohort C1: OPEN Cohort D: CLOSED Cohort E: CLOSED
TAPUR	OPEN	Patel/Elizabeth	---------	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)	**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
NX-1607-101	*OPEN*	Weiss/Elizabeth	Casitas B-lineage lymphoma proto-oncogene (CBL-B) inhibitor	*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*	***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*

NCI 10486	OPEN	Patel/Elizabeth	the BET inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib	Phase 2 Trial of the Combination of the BET inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib, in Patients with Molecularly-Selected Solid Tumors (ComBET)	Must have metastatic, unresectable disease, not candidates for SOC. **Biopsy is required**. Mutations included are: **Cohort 1**: BRCA1 or BRCA2; **Cohort 2**: BARD1, FANCA, BRIP1, PALB2, RAD51, RAD51C, RAD51D, with no evidence of mutations in BRCA1 or BRCA2; **Cohort 3:** C patients who have had PR/CR on prior PARPi monotherapy or PARPi combination treatment; (ii) patients with no evidence of BRCA1 or BRCA2 mutations or any of the relevant DDR aberrations listed in cohort 2; and (iii) patients with no intervening therapy following prior PARP inhibitor-based treatment;	
PBI-MST-01 (Presage)	*Open*	Sheth/Olivia	***MEDICAL DEVICE TRIAL, NO THERAPUTIC INTENT***- *Phase 0 trial for patients scheduled for tumor excision*	*A Phase 0 Master Protocol Using the CIVO® Platform to Evaluate Intratumoral Microdoses of Anti-Cancer Therapies in Patients With Solid Tumors*	**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.
PT217X1101 (Phanes)	*OPEN*	Weiss/ Elizabeth	Bispecific antibody (bsAb) against Delta like canonical Notch ligand (DLL3) and cluster of differentiation 47 (CD47)	*A Phase 1 Open-label, Multicenter, Dose Escalation and Dose Expansion Study of PT217 in Patients with Advanced Refractory Cancers Expressing DLL3*	Histologically or cytologically confirmed unresectable advanced or metastatic small cell lung cancer (SCLC), large cell neuroendocrine cancer (LCNEC), neuroendocrine prostate cancer (NEPC) and gastroenteropancreatic neuroendocrine carcinomas (GEP-NEC), previously treated with all existing standard of care treatments	More information upon opening
EGFR-008-001 (Janux)	*OPEN*	Weiss/ Olivia	recombinant tri-specific biologic, which binds epidermal growth factor receptor (EGFR), cluster of differentiation 3 (CD3), and albumin	*An Open-Label, Multicenter, Phase 1/1b Study of JANX008 in Subjects with Advanced or Metastatic Solid Tumor Malignancies*	Metastatic NSCLC, SCCHN, CRC, or RCC that are EGFR positive	More information upon opening
1042-CLN01 (Iconovir)	*ON INTERNAL HOLD*	Sheth/Olivia	Oncovirus	*Phase 1 First-in-Human Dose Escalation and Expansion Study to Assess Safety and Tolerability of Intravenous Administration of ICVB-1042 in Patients with Advanced Solid Tumors*	• Histological or cytologically confirmed solid tumor malignancy that is locally advanced or metastatic. • Progression on or after at least one prior standard of care (SOC) therapy including immune checkpoint inhibitors and therapies	
LCCC 1937	OPEN	Ishizawar/			**Key Eligibility:**	

				Immuno-Oncology Database and Bioregistry: Identifying mechanisms of autoimmune diseases in the era of cancer immunotherapy	- Diagnosis of cancer, pathology or imaging corroboration preferred but not required if cancer care team is starting ICI treatment -Starting initial ICI therapy (treatment naive) or re-starting ICI treatment after a 2-year gap in ICI treatment (including off-label use) at UNC-CH using any currently approved ICI's (Table 1). Prior conventional therapy (chemo, radiation, surgery) is allowed	
LCCC1736 (GI/Melanoma)	OPEN	Moschos/Doug	**Ulixertinib and Palbociclib** - Ulixertinib is a small molecule that potently inhibits both ERK1 and ERK2 protein kinases in the sub-nanomolar range, while not significantly inhibiting any of an array of kinases even at 1000-fold greater concentrations. Ulixertinib potently inhibits growth and survival in cultured cancer cell lines; melanoma, colorectal and pancreatic lines harboring BRAF or RAS mutations are among those most susceptible to the drug.	A Phase I Trial of Ulixertinib (BVD-523) in Combination with Palbociclib in Patients with Advanced Solid Tumors with Expansion Cohort in Previously Treated Metastatic Pancreatic Cancer and Metastatic RAS-mutant Melanoma	**Expansion Cohort:** Histologically confirmed unresectable stage III or stage IV melanoma with the following additional eligibility requirements: -Molecular profiling documenting any of the following genetic aberrations: NRASG12/G13/Q61, KRASG12/G13, HRASG12/G13, any amplifications of the NRAS, KRAS, or HRAS genes - Documented disease refractory to at least one PD1/PD-L1 inhibitor - Previously received treatment with ipilimumab	Inquire with Twomey/Griffin
RGX-202-001 (GI)	OPEN	Sanoff/Griffin and Jones	**RGX-202-01 + FOLFIRI + Bev** - RGX-202-01 is a small molecule inhibitor of the creatine transporter, SLC6a8, a novel metabolic pathway that drives gastrointestinal cancer progression. RGX-202-01 is the hemi-succinate salt of RGX-202 (also known as the endogenous compound, β-guanidinopropionic acid or β-GPA). RGX202-01 tablets will be administered PO.	A phase I study of RGX-202-01, small molecular inhibitor of creatine transporter with FOLFIRI	**Expansion Phase:** -2nd line CRC with FOLFIRI + Bev + RGX -Could have received only one prior regimen considered SOC for colorectal cancer in the advanced/metastatic setting, and it must have been an oxaliplatin-containing regimen	~12 slots as of 5/3/23, Have Griffin/Jones check with sponsor
NCI10464 (GI)	PENDING/ NEW	Somasundaram/Hairston	**Olaparib with Druvalumab and Concurrent RT**	A Phase 1 Study of Olaparib in Combination with Durvalumab (MEDI4736) and Concurrent Radiation Therapy Following First-Line Chemotherapy in Locally Advanced Unresectable Pancreatic Cancer	Locally Advanced Unresectable Pancreatic Cancer on First-Line Chemotherapy for At Least 16 weeks Without Progression	

NCI10522 (GI)	PENDING/ NEW	Somasundaram/Griffin	**CA-4948 with Gemcitabine and Nab-Paclitaxel** - CA-4948 (also known as AU-4948 in nonclinical studies) is a synthetic novel, orally available small molecule that is a potent and selective inhibitor of the interleukin-1 receptor-associated kinase 4 (IRAK4) and FMS-like tyrosine kinase 3 (FLT3).	A Phase 1 Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma	**2nd line metastatic or unresectable PDAC** **Part A: Dose Escalation (up to 18)** CA4948 +gemcitabine/nab-paclitaxel (D1, 8 q21d) **Part B: Dose Confirmation/Expansion (up to 18)** Gemcitabine/nab-paclitaxel + CA4948 3 cycles	
ZL-1211-001 (GI)	PENDING/ NEW	Somasundaram/Griffin	**ZL-1211** - ZL-1211 is a humanized IgG1 monoclonal antibody that was discovered by Zai BioPharma. ZL-1211 specifically binds to CLDN18.2 on the cell surface and is engineered to carry a mutation in the Fc region that drives enhanced ADCC and CDC.	A Phase I/II, First-in-Human, Open-Label, Dose Escalation Study of ZL-1211 in Patients with Unresectable or Metastatic Solid Tumor	**Phase I: Dose Escalation** **Phase II: Cohort Expansion** Cohort A: GC/GEJ (15-40) Cohort B: Pancreatic (15-40) Cohort C: Other solid tumors (15-40)	
AT148007/ ASPEN (GU)	OPEN	Milowsky/Messenger	**ALX148 with Enfortumab Vedotin and/or Other Anticancer Therapies** - ALX148 is a fusion protein comprised of the N-terminal D1 domain of SIRPα variant 1 (v1) genetically linked to a modified Fc domain from human immunoglobulin G (IgG1).	A Phase 1, Open-label, Multicenter, Safety, Pharmacokinetic, Pharmacodynamic Study of ALX148 in Combination with Enfortumab Vedotin and/or Other Anticancer Therapies in Subjects with Urothelial Carcinoma	**Phase 1a: Dose Escalation (15 per dose level)** Dose Level 1: ALX148 20mg/kg IV Q2W + Enfortumab vedotin Dose Level 2: ALX148 30 mg/kg IV Q2W + Enfortumab vedotin	Inquire with Messenger
LOXO-FG3-22001 (GU)	PENDING/ NEW	Milowsky/Holmes	**LOXO-435** - LOXO-435 is a potent, isoform-selective inhibitor of FGFR3 that is being developed to treat advanced solid tumors, including advanced urothelial cancer, with activating gene alterations in FGFR3.	A Phase 1 a/b study of LOXO-435 in advanced solid tumor malignancies with FGFR3 alterations	**Dose Escalation** *Cohort A:* All Solid Tumors (LOXO-435 monotherapy) **Dose Expansion Cohorts** *Cohort B:* Urothelial Carcinoma *B1:* LOXO-435 monotherapy (have received prior FGFR inhibitor) *B2:* LOXO-435 monotherapy (FGFR inhibitor naïve) *B3:* LOXO-435 + Pembrolizumabv(FGFR inhibitor naïve) *Cohort C:* All Non-urothelial Advanced Solid Tumors *C1:* LOXO-435 monotherapy (FGFR inhibitor naïve)	Inquire with Holmes

CT-0508-101 (CARISMA)	OPEN	Abdou/ Cheng (CT pod)	**CT-0508:** Adenovirally transduced autologous macrophages engineered to contain anti-HER2 chimeric antigen receptor (CAR-M)	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	**Group 1:** first 9 patients- intra-subject dose escalation of IV administrations of CT-0508 up to 0.5 x 10^9 cells on Day 1, up to 1.5 x 10^9 cells on Day 2, and 3 x 10^9 cells on Day 5 **Group 2**: if no more than 2 DLTs are observed in Group 1, enrollment will begin on Group 2; approximately 9 patients will receive up to 5 x 10^9 CT-0508 cells on Day 1	Slots available.
LCCC 1743-ATL	OPEN	Hucks/ Babinec (CT pod)	**iC9.GD2.CAR.IL-15 T cells:** GD2-directed chimeric antigen receptor T-cells (CAR-T), containing both IL15 cassette and inducible caspase 9 (iC9) safety switch	A Phase I Study of Autologous Activated T-Cells Expressing a 2nd Generation GD2 Chimeric Antigen Receptor, IL-15, and iCaspase9 Safety Switch Administered To Patients with Relapsed/Refractory Neuroblastoma or Relapsed/Refractory Osteosarcoma	**Exploring 6 different dose levels in pediatric cohorts** (0.5 x 10^6 to 1.0 x 10^7 cells/kg) **and 4 different dose levels in adult cohort** (2.5 x 10^6 to 1.0 x 10^7 cells/kg)	Slots available. Currently enrolling to Dose Level 1 in adult cohorts and Dose Level 3 in pediatric cohorts

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