## Studies Open at LAG 05/01/24 Hematology Studies

#### Please contact Team manager Christine Duran (duran c@med.usc.edu)

for status of suspended studies

Study Number	Study Title	PI
NC-HEM-05-4	Hematology Database (Contact: Abraham Syed)	Casey O'Connell
0S-15-16	Immunology Specimen Collection from Cancer Patients, Patients with Immune-Mediated Hematologic Diagnoses, and Healthy Normal Volunteers (Contact: Abraham Syed)	Casey O'Connell
16M-18-2	Phase II Multi-Institutional Study of Low-Dose (4Gy) Palliative Radiotherapy in the Treatment of Symptomatic Bone metastases from Multiple Myeloma	Adam Garsa
16M-22-1 (Temporarily Suspended)	A Phase 1b/2 Study of Standard Doses of Bortezomib and Pembrolizumab ± Reovirus (Pelareorep) Combination Therapy in Patients with Relapsed Multiple Myeloma (AMBUSH Study)	Kevin Kelly
NC-HEM-23-1	A Phase 1b, Open-Label Study to Assess the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Povetacicept in Subjects with Autoimmune Cytopenias (ITP, wAIHA, and CAD) (RUBY-4 study)	Caroline Piatek
9L-22-2	A Phase 2a, Randomized, Open-Label Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ISIS 702843 Administered to Patients with Phlebotomy Dependent Polycythemia Vera (PD-PV)	Casey O'Connell
9L-22-7	Assessment of Cognitive Function in Patients with Myeloproliferative Neoplasms (Contact: Abraham Syed)	Caitlin O'Neill
NC-HEM-19-7	Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study with a Long-term Open-label Extension *Approved for Consenting Only. Study procedures to be done at USC/Norris.	Howard Liebman

## Studies Open at LAG 05/01/24 Hematology Studies

#### Please contact Team manager Christine Duran (duran c@med.usc.edu)

for status of suspended studies

Study Number	Study Title	PI
9L-17-13	PhI-92: (NCI 10075) A Phase 1B Study of KRT-232 (AMG-232)	Kevin Kelly
(needs a slot)	in Combination with Decitabine and Venetoclax in Acute	
	Myeloid Leukemia	
9L-18-9	A Phase 2 Study of Ibrutinib and Blinatumomab in Relapsed	George
(needs a slot)	and Refractory B-Cell Acute Lymphoblastic Leukemia	Yaghmour

#### **Genitourinary Studies**

Please contact Team manager Xiomara Menendez (xiomara.menendez@med.usc.edu)

for status of suspended studies

Study Number	Study Title	PI
4B-15-11	A phase II trial of sEphB4-HAS in combination with anti PD1 antibody (pembrolizumab, MK-3475) for solid tumors	Sarmad Sadeghi
CTSU-AGCT 1532	A randomized phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor- risk metastatic germ cell tumors	Anishka D'Souza
CTSU-EA8134	3mpact – International penile advanced cancer trial (International Rare Cancers Initiative Study): 3mpact- neoadjuvant	Anne Schuckman
NRG-GU010	Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De- Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)	Jennelle
SWOG \$1802	Phase III randomized trial of standard systemic therapy (SST) versus standard systemic therapy plus definitive treatment (surgery or radiation) of the primary tumor in metastatic prostate cancer	Siamak Daneshmand
NRG-GU008	Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging Into Salvage Treatment for Patients with Node-Positive Prostate Cancer After Radical Prostatectomy	Jennelle
NRG-GU011	A Phase II Double-Blinded, Placebo-Controlled Trial of PROstate OligoMETastatic RadiotHErapy With or Without Androgen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG Promethean)	Jennelle
4P-22-2	Longitudinal Advanced Prostate Cancer Cohort (LAPCC)	Goldkorn

## Studies Open at LAG 05/01/24 GYN Studies

Please contact Team manager Kim Arieli (Kimberly.Arieli@med.usc.edu) for status of suspended studies

Study Number	Study Title	PI
5GYN-10-3	Banking Tissues from Normal and Disease-Related Gynecologic Surgeries	Linda Roman
NRG-CC008	A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-Oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROCk]	Koji Matsuo
5GYN-23-2	A Phase 1B/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 <sup>®</sup> Status	Koji Matsuo

### **Breast Studies**

Please contact Team manager Kim Arieli (Kimberly.Arieli@med.usc.edu) for status of suspended studies

Study Number	Study Title	PI
A211801	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, International Phase 3 Study to Determine the Preventive Effect of Denosumab on Breast Cancer in Women Carrying a <i>BRCA1</i> Germline Mutation (BRCA-P)	Darcy Spicer
1B-10-3	Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2.	Evanthia Torres/ Fumito Ito (Co-I)
1B-21-1	A Randomized, Phase II Trial of Circulating Tumor DNA- Guided Second Line Adjuvant Therapy For High Residual Risk, Stage II-III, Estrogen Receptor Positive, HER2 Negative Breast Cancer (DARE)	Evanthia Roussos Torres
0S-04-7	USC Tumor and Tissue Bank	Michael Press
1B-11-1	Breast Cancer Blood Biorepository	Evanthia Roussos Torres
1B-13-2	Core Biopsies of Breast Tumor Tissue Repository.	Evanthia Roussos Torres
CTSU-CCTG MA.39	A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer	Jason Ye
1B-21-3	A Global, Phase 2 Study of ARX788 in HER2-positive Metastatic Breast Cancer Patients who were Previously Treated with T-DXd	Priya Jayachandran
1B-21-8	A Randomized, Multicenter, Placebo-controlled, Phase 3 study to Evaluate the Efficacy and Safety of HER2/neu Peptide GLSI-100 (GP2 + GM-CSF) in HER2/neu Positive Subjects with Residual Disease or High-Risk PCR after both Neoadjuvant and Postoperative Adjuvant Trastuzumab- based Therapy (FLAMINGO-01)	Danielle Sterrenberg
1B-22-2	A Phase I Study of In Situ Immunomodulation with CDX- 301, Radiotherapy, CDX-1140 and Poly-ICLC in Patients with Unresectable and Metastatic Solid Tumors with Injectable Palpable Disease	Fumito Ito

#### **Breast Studies**

Please contact Team manager Kim Arieli (Kimberly.Arieli@med.usc.edu) for status of suspended studies

Study Number	Study Title	PI
NRG-BR007	A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)	Shelly Bian
CTSU-EA1151	Comparison of Tomosynthesis to Digital Mammography in Breast Cancer Screening	Linda Hovanessian
CTSU-EA1211	Interim FDG-PET/CT for PreDIcting REsponse of HER2+ Breast Cancer to Neoadjuvant Therapy: DIRECT trial	Peter Conti
1B-19-5	Characterizing Breast Masses Using an Integrative Framework of Machine Learning and Radiomics	Bino Varghese
1B-22-1	Clinical Utility of Fluoroestradiol F18 PET/CT in Metastatic Breast Cancer Patients with ER-Positive and HER2-Negative Primary Lesions after Progression on First Line Hormonal Therapy	Peter Conti

#### **Gastrointestinal Studies**

Please contact Team manager **Charlean Ketchens (<u>ketchens\_c@med.usc.edu</u>)** for status of suspended studies

Study Number	Study Title	PI
0C-20-10	A Phase 1b Study Evaluating the Safety, Tolerability, and Efficacy of AMG 510 (pINN Sotorasib) in Combination with MVASI and FOLFIRI and in Combination with MVASI and FOLFOX in Subjects with Advanced Colorectal Cancer with KRAS p.G12C Mutation (sub-protocol M)	Anthony El- Khoueiry
0C-23-11	Brightline-2: A Phase IIa/IIb, open-label, single-arm, multi- centre trial of BI 907828 for treatment of patients with locally advanced / metastatic, MDM2 amplified, TP53 wild- type biliary tract adenocarcinoma, pancreatic ductal adenocarcinoma, or other selected solid tumours	Anthony El- Khoueiry
3BD-23-1	A Phase 2/3 Randomized, Controlled Study of CTX-009 in Combination with Paclitaxel versus Paclitaxel Alone in Adult Patients with Unresectable Advanced, Metastatic or Recurrent Biliary Tract Cancers who have received One Prior Systemic Chemotherapy Regimen	Anthony El- Khoueiry
3C-20-6	An open-label, multicenter, randomized phase 3 study of first-line encorafenib plus cetuximab with or without chemotherapy versus standard of care therapy with a safety lead-in of encorafenib and cetuximab plus chemotherapy in participants with metastatic BRAFV600E-mutant colorectal cancer	Heinz-Josef Lenz
3C-21-3	USC Center for Optimization of Participant Engagement for Cancer Characterization (COPECC)	Heinz-Josef Lenz
3C-22-5 Temp suspended	A Phase 1b/2, Open-Label Study of Amivantamab Monotherapy and in Addition to Standard-of-Care Chemotherapy in Participants with Advanced or Metastatic Colorectal Cancer	Heinz-Josef Lenz
3C-23-2	A Longitudinal Cohort for Locally Advanced Colorectal Cancer	Heinz-Josef Lenz
3C-23-5	An Open-label Randomized Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or	Heinz-Josef Lenz

#### **Gastrointestinal Studies**

Please contact Team manager **Charlean Ketchens (<u>ketchens\_c@med.usc.edu</u>)** for status of suspended studies

Study Number	Study Title	PI
	Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer.	
3C-23-6	A Phase I/II, Multicenter, Open-Label Study of Nous-209 Genetic Vaccine for the Treatment of Microsatellite Unstable Solid Tumors	Sandra Algaze
3C-23-10	A Phase 2, Randomized, Open-label Study of Onvansertib in Combination with FOLFIRI and Bevacizumab or FOLFOX and Bevacizumab Versus FOLFIRI and Bevacizumab or FOLFOX and Bevacizumab for the First-line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS or NRAS Mutation	Heinz-Josef Lenz
3G-21-1	Ramucirumab Plus Trifluridine/Tipiracil (TAS-102) for Patients with Previously Treated Advanced Gastric or Gastroesophageal Junction Adenocarcinoma: An Investigator-Initiated, Randomized Non-Inferiority Phase 2 Study	Syma Iqbal
3G-21-2	An Open-Label, International, Multicenter, Phase 1b Study to Assess the Safety, Tolerability, and Efficacy of IDX-1197 in Combination with Xelox (Capecitabine and Oxaliplatin) or Irinotecan in Patients with Advanced Gastric Cancer	Syma Iqbal
3G-22-1	A Phase 2 Trial to Evaluate the Safety and Efficacy of Domvanalimab (AB154) and Zimberelimab (AB122) and Based Treatment Combinations in Patients with Advanced Upper Gastrointestinal Tract Malignancies	Syma Iqbal
3L-22-1 Temp Suspended- Amendment	A Phase 1/2, Safety Confirmation and Double-Blind, Randomized Study of Relatlimab in Combination with Nivolumab and Bevacizumab in Treatment-Naive Advanced/Metastatic Hepatocellular Carcinoma (RELATIVITY-106)	Anthony El- Khoueiry
3L-23-1	A Phase 1b/2 Multicenter, Open-label Study to Evaluate the Safety and Efficacy of TTI-101 as Monotherapy and in Combination in Participants with Locally Advanced or Metastatic, and Unresectable Hepatocellular Carcinoma	Anthony El- Khoueiry

#### **Gastrointestinal Studies**

Please contact Team manager **Charlean Ketchens (<u>ketchens\_c@med.usc.edu</u>)** for status of suspended studies

Study Number	Study Title	PI
CTSU-A022104	The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing the Efficacy of Triplet versus Doublet Chemotherapy to Achieve Clinical Complete Response in Patients with Locally Advanced Rectal Cancer	Diane Ling
CTSU-EA2174 Temp Suspended	A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma	Syma Iqbal
CTSU-EA2176	A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naive Metastatic Anal Cancer Patients	Syma Iqbal
NRG-GI008	Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-US)	Sandy Algaze
SWOG-S2104	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High- Risk Pancreatic Neuroendocrine Tumors	Syma Iqbal

## Studies Open at LAG 05/01/24 Lung+ H & N Studies

#### Please contact Team manager Sandy Tran (Sandy.Tran@med.usc.edu) for status of suspended studies

Study Number	Study Title	PI
2N-21-9	ML43326 - A phase II study of subcutaneous atezolizumab in NSCLC patients using a decentralized clinical trial model.	Jorge Nieva
2N-23-3	A Randomized, Double-blind, Multi-center, Phase III Study of AK112 or Placebo Combined with Pemetrexed and Carboplatin in Patients with EGFRmutant Locally Advanced or Metastatic Non-squamous NSCLC Who Have Failed to EGFR-TKI Treatment (HARMONi)	Robert Hsu
7H-22-3	NCI# 10496 PhII-216 entitled, "A Phase 2 Study of Ipatasertib in Combination with Pembrolizumab for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (3.7.22v).	Jacob Thomas
7h-23-1	NCI 10553/ PhII-232: 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.	Jacob Thomas
NRG-CC009	NRG-CC009: Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA- WBRT) for 10 or fewer Brain Metastases from Small Cell Lung Cancer	Jason Ye
SWOG-S1827	"MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)"	Jason Ye

## Melanoma/Sarcoma Studies

Please contact Team manager Sandy Tran (Sandy.Tran@med.usc.edu) for status of suspended studies

Study Number	Study Title	PI
05-20-1	Short-term Fasting Prior to Standard Checkpoint Blockade Using PD-1/PD-L1 Inhibition: a Pilot Safety and Feasibility Study	Gino In
CTSU-A091903	A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma	Gino In
14SK-19-1	Evaluating the PD-1 checkpoint inhibitor, Cemiplimab, as neoadjuvant therapy in high risk localized, locally recurrent, and regionally advanced cutaneous squamous cell carcinoma: a Phase II pilot study	Gino In
14SK-20-1	A Randomized, Placebo-Controlled, Double-Blind Study of Adjuvant Cemiplimab Versus Placebo after Surgery and Radiation Therapy in Patients with High Risk Cutaneous Squamous Cell Carcinoma study	Gino In
14Sk-22-1	First-in-Human, Phase 1/1b, Open-label, Multicenter Study of Bifunctional EGFR/TGFβ Fusion Protein BCA101 Monotherapy and in Combination Therapy in Patients with EGFR-Driven Advanced Solid Tumors	Gino In
0C-20-3 Suspended	A Phase 1, First-in-human, Open-label, Dose-escalation, Safety, Pharmacokinetic, and Pharmacodynamic Study of Oral TP-1287 Administered Twice Daily to Patients with Advanced Solid Tumors	James Hu
115-22-2	Brightline-1: A Phase II/III, randomized, open-label, multi-center study of BI 907828 compared to doxorubicin as first line treatment of patients with advanced dedifferentiated liposarcoma	James Hu
11S-23-1 Suspended	NCI 10556: Randomized Phase 2 Study of Cabozantinib, Ipilimumab, and Nivolumab in Patients with Soft Tissue Sarcoma	James Hu

#### Neuronc

Please contact Team manager Sandy Tran (Sandy.Tran@med.usc.edu) for status of suspended studies

Study Number	Study Title	PI
6G-15-2	An Open-Label, Phase 1/2a Dose Escalation Study of Safety and Efficacy of NEO100 in Recurrent Grade IV Glioma	Frances Chow
6G-22-1	A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib in Participants With Previously Treated Glioblastoma or Other Primary Central Nervous System Tumors Harboring Activating FGFR1-3 Alterations (FIGHT-209)	Frances Chow
6G-22-4	PhII-222 / 10505: A Phase 1 and Randomized Phase 2 Trial of Selinexor and Temozolomide in Recurrent Glioblastoma	Frances Chow
6M-22-1	An Open-Label, Phase 2 Study of Neo100 in Participants with Residual, Progressive or Recurrent High-Grade Meningioma	Frances Chow
NRG-BN010 Suspended	NRG-BN010: A SAFETY RUN-IN AND PHASE II STUDY EVALUATING THE EFFICACY, SAFETY, AND IMPACT ON THE TUMOR MICROENVIRONMENT OF THE COMBINATION OF TOCILIZUMAB, ATEZOLIZUMAB, AND FRACTIONATED STEREOTACTIC RADIOTHERAPY IN RECURRENT GLIOBLASTOMA	Lindsay Hwang

For ph1 program trials, if you have a potential patient, please email:<u>NeedASlot@med.usc.edu</u> to have patient evaluated for studies in this program.

Study Number Pl	Study Title	Tumor Types
0C-14-9	A Modular Phase I, Open-Label, Multicentre Study	Ovarian
PI: Dr. El-Khoueriy	to Assess the Safety, Tolerability, Pharmacokinetics	
	and Preliminary Anti-tumour Activity of Ascending	Module 5
	Doses of AZD6738 in combination with Cytotoxic	
	Chemotherapy and/or DNA Damage Repair/Novel	
	Anti-cancer Agents in Patients with Advanced Solid	
	Malignancies	
	Tx: ATM inhibitor /ATR kinase + Durvalumab	
0C-18-2	Study FID-007-001: A Phase I Study of FID-007 in	All solid tumors
PI: Dr. El-Khoueiry	Patients with Advanced Solid Tumors (FULGENT) a	
	PEOX nanosomal encapsulated taxol	
0C-19-7	A Ph1 study of AGEN1181, an Fc-Engineered anti	NSCLC, Fibrolamellar, HCC
PI: Dr. El-Khoueiry	CLA-4 Monoclonal Antibody in Pts with advanced	
	cancers and select tumor types	
	AGEN1181: (CTLA-4) human monoclonal antibody	
0C-20-1	A Phase I/II, First-In-Human, Multi-Part, Open-	Tumors targeting HER2
PI: Dr. El-Khoueiry	Label, Multiple-Ascending Dose Study to Investigate	
	the Safety, Tolerability, Pharmacokinetics,	
	Biological, and Clinical Activity of DF1001 in Patients	
	With Locally Advanced or Metastatic Solid Tumors,	
	and Expansion in Selected Indications	
	TriNKET tri-specific antibody that binds to NK cells,	
	cytotoxic T cells and Her2.	

For ph1 program trials, if you have a potential patient, please email:<u>NeedASlot@med.usc.edu</u> to have patient evaluated for studies in this program.

Study Number PI	Study Title	Tumor Types
0C-20-10 Pl: Dr. El-Khoueiry	TPX-0005-13 Phase 1b/2 Study of Repotrectinib in Combination with Other Anticancer Therapies for the Treatment of Subjects with KRAS-Mutant Advanced Solid Tumors (TRIDENT-2) oral agents: KRAS G12D	Sub-protocol F: NSCLC only Sub-protocol J (palbociclib): (CRC, NSCLC, Other Solid Tumors) Sub-protocol M (Mvasi): CRC only
0C-20-24 Pl: Dr. El-Khoueiry	ABL503 bispecific antibody (BsAb), ABL503 (PD-L1 and 4- 1BB). A Phase 1 Dose-escalation and Expansion Study of ABL503, a Bispecific Antibody of 4-1BB and PD-L1 as a Single Agent in Subjects with Advanced Solid Tumors	Solid tumors & NSCLC
0C-21-9 PI: Dr. El-Khoueiry	A Phase 1a/1b Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	Currently in Ph1b
OC-21-12 PI: Dr. El-Khoueiry	A Dose Escalation Study of HFB301001 (OX40 Agonist Antibody) in Adult Patients with Advanced Solid Tumors	Sarcoma, RCC, urothelial, bladder, HCC, HNSCC
0C-22-7 PI: Dr. J. Thomas	A Phase 2 multi-center open-label basket trial of nab-sirolimus for adult and adolescent patients with malignant solid tumors harboring pathogenic inactivating alterations in TSC1 or TSC2 genes.	Solid tumors

### Phase I

For ph1 program trials, if you have a potential patient, please email:<u>NeedASlot@med.usc.edu</u> to have patient evaluated for studies in this program.

Study Number Pl	Study Title	Tumor Types
OC-21-20 Pl: Dr. El-Khoueiry	HFB-200301-01 A Phase 1, Open-Label, Multi-Center, Dose Escalation and Expansion Study of HFB200301 (TNFR2 Agonist Antibody) in Adult Patients with Advanced Solid Tumors	NSCLC, melanoma, urothelial, bladder, Breast, TNBC
OC-22-11 PI: Dr. Thomas	A PHASE 1/2 STUDY OF BA3071 AS MONOTHERAPY AND IN COMBINATION WITH A PD-1 BLOCKING ANTIBODY IN PATIENTS WITH ADVANCED SOLID TUMORS	AST, Melanoma, RCC, NSCLC, urothelial, gastric, SCLC, HCC, cervical
OC-22-19 Pl: Dr. El-Khoueiry	A Phase I, Multicenter, Open-label, Dose- Escalation, Safety, Pharmacodynamic and Pharmacokinetic Study of AU409 Dosed Orally Once Daily in Patients with Selected Advanced Solid Tumors	All solid tumors
0C-20-16 Pl: Dr. El-Khoueiry	A Phase 1, Multicenter, Open-label, Dose- Escalation, Safety, Pharmacodynamic, Pharmacokinetic Study of Q702 with a Cohort Expansion at the RP2D in Patients with Advanced Solid Tumors Q702 is a novel, orally active, small molecule inhibitor that targets Axl, Mer, and CSF1R	All solid tumors
0C-22-3 Pl: Dr. El-Khoueiry	A Phase 1/2, Open-Label, Single-Arm, Dose- Escalation and Dose-Expansion Study of the Safety, Tolerability, Pharmacokinetic, and Antitumor Activity of E-602 as a Single Agent and in Combination with Pembrolizumab in Patients with Advanced CancersE-602 is a Glycan Mediated Immune Regulation with a Bi-Sialidase Fusion Protein (GLIMMER-01)	melanoma, ovarian, NSCLC, CRC, pancreatic, TNBC, gastric, HN, urothelial

### Phase I

For ph1 program trials, if you have a potential patient, please email:<u>NeedASlot@med.usc.edu</u> to have patient evaluated for studies in this program.

Study Number Pl	Study Title	Tumor Types
0C-22-4 PI: Dr. Hanna	Phase 1/2, Open-Label Study of in Patients with Advanced Solid Tumors targets IL2	All solid tumors
0C-22-6 Pl: Dr. El- Khoueiry	A Phase 1/2, Open Label, Dose Escalation and Expansion Study of Tac-001 In Patients with Select Advanced or Metastatic Solid Tumors	melanoma, breast, ovarian, CRC, NSCLC, RCC, HN, merkel, HCC, cervical, urothelial, endometrial, gastroesophageal, cholangio
0C-22-9 Pl: Dr. El-Khoueiry	A Phase 1/2 Multicenter, Open-label, Dose- escalation, Safety, Pharmacodynamic, and Pharmacokinetic Study of Q901 Administered via Intravenous Infusion in Adult Patients with Selected Advanced Solid Tumors with a Cohort Expansion at the Recommended Phase 2 Dose Q901: small molecule inhibitor for CDK7 kinase activity	Ovarian, prostate, breast, CRC, SCLC, pancreatic
0C-20-7 Pl: Dr. El-Khoueiry	A Phase 1, First-in-human, Open-label, Dose- escalation, Safety, Pharmacokinetic, and Pharmacodynamic Study of Oral TP-1454Single agent cohort 1- oral small molecule activator of PKM2	Anal cancer
0C-22-15 Pl: Dr. J.Thomas	A Phase 1 Open-label, Multicenter, Dose- ranging Study to Investigate Safety and Tolerability, Efficacy, Pharmacokinetics, Pharmacodynamics, and Immunogenicity of MT-6402 in Subjects with Advanced Solid Cancer That Expresses PD-L1	All solid tumors

For ph1 program trials, if you have a potential patient, please email:<u>NeedASlot@med.usc.edu</u> to have patient evaluated for studies in this program.

Study Number PI	Study Title	Tumor Types
0C-22-16	A Phase 1B/2, Open-label Study of Q702 in	Esophageal, gastric, HCC,
PI: Dr. El-Khoueiry	combination with intravenous Pembrolizumab in	cervical
	Patients with Selected Advanced Solid Tumors	
0C-20-18	A Phase 1/2 Open-label, Multicenter Study to	Solid tumors with P53 Y220C
PI: Dr. El-Khoueiry	Assess the Safety, Tolerability, Pharmacokinetics,	mutation
	Pharmacodynamics, and Efficacy of PCXXX in	
	Patients with Advanced Solid Tumors Harboring a	
	p53 Y220C Mutation	
0C-22-20	A Phase 1/2, First-In-Human, Multi-Part, Open-	All solid tumors
PI: Dr. Hanna	Label Study to Investigate the Safety, Tolerability,	
	Pharmacokinetics, Biological and Clinical Activity	
	of DF9001 as a monotherapy and in combination	
	with nivolumab in Patients With Advanced	
	(Unresectable, Recurrent, or Metastatic) Solid	
	Tumors, and Expansion in Selected Indications	
0C-23-4	TT-10-101	RCC, CRPC, NSCLC
PI: Dr. El-Khoueiry	Phase I/II First-in-Human Study of TT-10 as a	
FI. DI. LI-KIIOUEITY	Single Agent in Participants with Advanced	
	Selected Solid Tumors	
	TT-10 is a novel, potent and selective adenosine	
	A2A receptor (A2AR) antagonist	
0C-23-5	A Study to Evaluate the Safety and Tolerability of	Biomarker, CRC, gastric,
PI: Dr. El-Khoueiry	the Covalent Phosphoinositide-3-Kinase	NSCLC, breast, HNSCC,
FI. DI. LI-KIIOUEII y	(PI3K)-alpha Inhibitor, TOS-358, in Adult Subjects	urothelial, ovarian, cervical,
	with Select Solid Tumors	endometrial
	TOS-358, a potent covalent inhibitor of wild-type	
	and mutant PI3Kα (oral agent)	

For ph1 program trials, if you have a potential patient, please email:<u>NeedASlot@med.usc.edu</u> to have patient evaluated for studies in this program.

Study Number PI	Study Title	Tumor Types
0C-23-6 PI: Dr. J. Thomas	Phase I Clinical Study on the Tolerability of Utidelone Capsule in Patients with Advanced Solid Tumors UTD2 has the same MoA as UTD1. With the molecular target of tubulin, the main MoA of utidelone is to work by directly binding to β- tubulin subunits on the microtubule	All Solid Tumors
0C-23-7 PI: Dr. El-Khoueiry	A Phase 1-2 dose-escalation and expansion study of ST316 in subjects with selected advanced unresectable and metastatic solid tumors ST316 is a novel peptide antagonist of the interaction between βcatenin and its co- activator BCL9	CRC, breast, NSCLC, ovarian, pancreatic, melanoma, cholangiocarcinoma, sarcoma
0C-23-9 PI: Dr. J. Thomas	Phase 1, First-in-Human, Multicenter, Open- Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Antitumor Activity of KO-2806 When Administered as Monotherapy and in Combination Therapy in Adult Patients with Advanced Solid Tumors Targets RAS family	HRAS-mutant and/or amplified tumors (any solid tumor type), HRAS overexpression (only HNSCC), KRAS and/or NRAS and/or HRAS-mutant and/or amplified NSCLC or CRC, KRAS-mutant or amplified PDAC
0C-23-15 PI: Dr. El-Khoueiry	A Phase 1a/b Study of ADRX-0706 in Subjects with Select Advanced Solid Tumors	UC, HNSCC, breast, cervical, ovarian, NSCLC, pancreas
0C-23-16 PI: Dr. J. Thomas	A Phase I/II, Open-Label, Multi-Center Study of ALE.CO4 (anti-Claudin-1 Antibody) as a Single Agent and in Combination with Pembrolizumab (anti-PD-1 antibody) in Adult Patients with Recurrent or Metastatic (R/M) Head and Neck Squamous Cell Carcinoma	HN