

USC/Kenneth Norris Cancer Center Protocols Oncology Protocol Priority List

(See separate list for Hematology)

Version Dated 05/03/2024 ds

P - Pasadena NB – Newport Beach H –HOAG
W – Westside TM – Team Manager
* - Protocol is Open to Accrual at Los Angeles General (LAGMC)

All or Multiple Sites

* **0C-14-9** Ph I anti-tumor activity of AZD6738 in solid tumors. TM: X. Menendez
* **0C-18-2** Ph1 of FID-007 in Pts w/ Adv. Solid Tumors (FULGENT). TM: X. Menendez
0C-18-21 Ph1b Study of TRK-950 +Sel Anti-Ca Tx in Sel Adv Solid Tumors. TM: X. Menendez
0C-19-1 Ph1-2 Safety, PK & Activity of ASTX029 in Advanced Solid Tumors. TM: X. Menendez
* **0C-19-7** Ph1 AGEN1181 in Adv CA. TM: X. Menendez
* **0C-20-1** Study of DF1001 in Patients With Advanced Solid Tumors. TM: X. Menendez
* **0C-20-7 (SUSPENDED)** Ph1/1b Dose-escalation, Safety, PK, PD Oral TP-1454 alone & Combination with Ipilimumab & Nivolumab. TM: X. Menendez
* **0C-20-10** AMG 510 in Subjects with Advanced Solid Tumors with KRAS p.G12C Mutation. TM: X. Menendez
0C-20-13 Ph 1-2 Intravenous Zotatfin (eFT226) in Solid Tumor. TM: X. Menendez
0C-20-14 TAPISTRY Phase II Platform trial. TM: X. Menendez
* **0C-20-16** Ph 1 Dose-Escalation, Safety, PD, PK Study of Q702 + Cohort Expansion at the RP2D in Solid Tumors. TM: X. Menendez
* **0C-20-18** Ph 1/2 Safety, Tolerability, PK, PD, + Efficacy of PC14586 in Adv Solid Tumors Harboring p53 Y220C Mutation. TM: X. Menendez
0C-20-19 Ph1/2 Dose Escalation + Dose Expansion of Ba3011 Alone & Combination with Nivolumab In Adult And Adolescent 12 Years+ With Advanced Solid Tumors. TM: X. Menendez
0C-20-22 Ph1 Study of SRF388 in Pts with Advanced Solid Tumors. TM: X. Menendez
* **0C-20-24** Ph 1 Dose Escalation & Expansion of ABL503 in Progressive Locally Advanced (Unresectable) or Metastatic Solid Tumors. TM: X. Menendez
0C-21-1(SUSPENDED) Ph1a/b Study of Mtl-Cebpa with Pembrolizumab in Adult Pts with Advanced Solid Tumors (Timepoint). TM: X. Menendez
0C-21-8 Ph1-129/NCI 10358: Ph1/1B Study of DS-8201a + AZD6738 in Advanced Solid Tumors w/ HER2 Expression (DASH Trial). TM: X. Menendez
* **0C-21-9** Ph1a/1b LY3537982 in Pts. w/ KRAS G12C-Mutant Advanced Solid Tx. TM: X. Menendez

0C-21-13 Ph1/2a Study of AFM24 in Combo with Atezo in Pts. With Selected Adv./Metastatic EGFR-Expressing Cancers. TM: X. Menendez.
0C-21-14 Ph1/2 Study of BA3021 Alone and in Combo with Nivo in Pts. With Advanced Solid Tumors. TM: X. Menendez.

0C-21-18 Ph1 Study of ASP1570 in Pts. w/ Adv. Solid Tumors. TM: X. Menendez
* **0C-21-20** Ph1 Study of HFB200301 (TNF2 Agonist Ab) in Adult Pts. With Adv. Solid Tumors. TM: X. Menendez.
* **0C-22-6** Ph1/2 Study of TAC-001 in Pts. w/ Select Adv. or Metastatic Solid Tumors. TM: X. Menendez
* **0C-22-7** Ph2 Multi-Center Open-Label Basket Trial of nab-Sirolimus in Pts w/ Malignant Solid Tx Harboring Pathogenic Inactivating Alterations in TSC1 or TSC2 Genes. TM: X. Menendez
* **0C-22-9** Ph1/2 Study of Q901 IV in Adult Pts. w/ Selected Adv. Solid Tx w/ a Cohort Expansion at the RP2D. TM: X. Menendez
0C-22-11 Ph1/2 Study of BA3071 in Combo w/ Nivo in Pts. w/ Adv. Solid Tumors. TM: X. Menendez
0C-22-12 Ph1 Study of Decoy20 in Pts. w/ Adv. Solid Tx. TM: X. Menendez
0C-22-13 Ph1 Study of HBM7008 in Subjects w/ Adv. Solid Tx. TM: X. Menendez
* **0C-22-15** Ph1 Open-Label Study of MT-6402 in Subjects w/ Adv Solid Cx Expressing PD-L1. TM: X. Menendez
* **0C-22-16** Ph1b/2 Study of Q702 in Combo w/ IV Pembro in Pts w/ Select Adv. Solid Tx. TM: X. Menendez
0C-22-17 Ph1/2 FIH Dose Esc. + Dose Exp. Study of SAR444200-Based Regimen in Pts. w/ Adv. Solid Tx. TM: X. Menendez.
* **0C-22-19** FIH Dose Esc. Study of AU049 in Pts. w/ Adv. Primary Liver Cancers or Adv. Solid Tx w/ Liver Predominant Metastatic Disease. TM: X. Menendez.
* **0C-22-20** Ph1/2 FIH Study of DF9001 as Monotx & in Combo w/ Nivo in Pts w/ Adv. Solid Tumors, Expansion in Selected Indications. TM: X. Menendez
0C-23-1 Open-label / Ph 1 / Safety, PK, & Efficacy of BA3182 (EpCAM)/CD3 Antibody in Advanced Adenocarcinoma. TM: X. Menendez
0C-23-2 Ph1a/1b Study of HFB200603 (anti-BLA aB) as Single Agent & in Combo w/ Tislelizumab (anti-PD-1 aB) in Adult Pts w/ Adv. Solid Tumors. TM: X. Menendez
0C-23-3 Ph1a Study of NX-1607, a Casitas B-lineage lymphoma proto-oncogene (CBL-B) inhibitor, in Adults w/ Adv. Malignancies w/ Ph1b Expansion in Select Tumor Types. TM: X. Menendez
* **0C-23-4 (SUSPENDED)** Ph1/2 FIH Study of TT-10 as Single Agent in Pts w/ Adv. Selected Solid Tumors. TM: X. Menendez
* **0C-23-5** Ph1 Study of TOS-358, Covalent Phosphoinositide-3-Kinase (PI3K)-alpha Inhibitor in Adult Subjs. w/ Select Solid Tx. TM: X. Menendez
* **0C-23-6** Ph1 Clinical Study on the Tolerability of Utidelone Capsules in Pts w/ Adv. Solid Tumors. TM: X. Menendez
* **0C-23-7** Ph1/2 Dose Escalation, Expansion Study of ST316 in Subjs w/ Selected Adv. Unresectable and Metastatic Solid Tumors. TM: X. Menendez
0C-23-8 Ph1/2 Study of TAC T-Cells in Subjs w/ Unresectable, Locally Adv. Or Metastatic Claudin 18.2+ Solid Tx. TM: X. Menendez
* **0C-23-9** Ph1 FIH Study of KO-2806 as Monotherapy and in Combo Therapy w/ Adult Pts w/ Adv. Solid Tumors. TM: X. Menendez

0C-23-10 Ph1 Study of CPO301 in Adult Pts w/ Adv. Or Metastatic Adv. Solid Tumors. TM: X. Menendez
0C-23-11 Ph2a/2b Study of BI907828 for Pts w/ Locally Adv. / Metastatic MDM2 amplified, TP53 WT Biliary Tract Adenocarcinoma, Pancreatic Ductal Adenocarcinoma or Other Solid Tumors. TM: C. Ketchens / Choi (KT)
0C-23-13 Ph 1/2, BMS-986340 +/- Nivolumab or Docetaxel in Advanced Solid Tumors. TM: X. Menendez
0C-23-14 Ph1 FIH Study of CLN-617 Alone and in Combo w/ Pembro in Pts w/ Adv. Solid Tumors. TM: X. Menendez
* **0C-23-15** Ph1a/1b Study of ADRX-0706 in Subjs w/ Select Adv. Solid Tumors. TM: X. Menendez
* **0C-23-16** Ph1/2 Study of ALE.C04 (anti-Claudin-1 ab) as Single Agent and in Combo w/ Pembro in Adult Pts w/ R/M HNSCC. TM: X. Menendez
0C-23-17 Ph1 FIH Study of KB-0742 in Pts w/ R/R Solid Tumors or NHL. TM: X. Menendez
0C-23-18 FIH, Open-label, Ph 1, Safety, Tolerability, PK, and PD of PYX-106 in Advanced Solid Tumors. TM: X. Menendez
0C-23-21 Ph2 Trial of BET Inhibitor ZEN003694 + PARP Inhibitor Talazoparib in Pts w/ Molecularly-Selected Solid Tumors (CombET). TM: X. Menendez / Massopust (NPB) / Choi (KT)
0C-23-22 Ph 1, FIH, Open-Label/ safety, PK & efficacy of ABBV-303, +/- budigalimab (ABBV-181) in advanced solid tumors. TM: X. Menendez
0C-23-24 Ph I Autologous CD8+ And CD4+ Engineered TCR T Cells in Advanced or Metastatic Solid Tumors. TM: X. Menendez
0C-23-25 Ph I/II, FIH, Open-Label/ Safety, Tolerability, PK, Immunogenicity & Preliminary Efficacy of LM-24C5 in Advanced Solid Tumors. TM: X. Menendez
0C-23-26 Ph 1 Study of NM32-2668 in Adults w/Selected Advanced Solid Tumors. TM: X. Menendez
0S-19-6 A Phase I/II Study of HB-201 Monotherapy or in Combination with Nivolumab in Patients with Human Papillomavirus 16 Positive (HPV 16+) Confirmed Cancers TM: S. Tran
* **0S-20-1** Short-term Fasting Prior to PD-1/PD-L1 Inhibitor Therapy for of Advanced or Metastatic Skin Malignancy. TM: S. Tran
0S-20-8 Ph 1/2 RP1 +PD1 Blockade in Patients with Solid Tumors. TM: C. Ketchens
0S-23-3 Ph1 Study of BET Bromodomain Inhibitor ZEN003694 in Combo w/ CDK4/6 Inhibitor Abemaciclib in Pts w/ NUT Carcinoma and Other Solid Tumors. TM: S. Tran / Massopust (NPB) / Choi (KT)
CTSU-A031702 Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC). TM: X. Menendez (INTERIM)
SWOG-S2013 Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study. TM: S. Tran

Breast

* **1B-10-3** Investigation of Serial Studies to Predict Your Therapeutic Response w/ Imaging & Molecular Analysis 2. TM: K. Arieli
* **1B-11-1** Bld Bio Repository. TM: K. Arieli / Massopust (NB)

1B-11-9 In Vivo Cell Proliferation by PET in Breast Ca. PI: Desai

* **1B-13-2** Core Bx Breast Repository. TM: K. Arieli

* **1B-21-1** Rand. Ph II ctDNA-guided 2L Adjuvant Therapy for High Residual Risk, Stage 2-3, ER+/HER2- Breast Cancer (DARE). TM: K. Arieli / Massopust (NB) / Choi (KT)

* **1B-21-3** Ph2 Study of ARX788 in HER+ mBRC Pts Previously Tx'ed w/ T-DXd. TM: K. Arieli

* **1B-21-8** Rand. Ph3 Study of HER2/neu Peptide GLSI-100 (GP2 + GM-CSF) in HER2/neu+ Subject3s with Residual Disease or High-Risk PCR after both Neoadj. and Postoperative Adj. Trastuzumab-based Therapy (FLAMINGO-01). TM: K. Arieli

* **1B-22-2** Ph1 Study of In Situ Immunomodulation w/ CDX-301, RT, CDX-1140 and Poly-ICLC in Pts w/ Unresectable and Metastatic Solid Tx w/ Injectable Palpable Disease. TM: K. Arieli

1B-22-3 Ph1 Dose Finding Study of Sarilumab + Capecitabine in HER2/neu-Negative mBRC and Ph2 Study of Sarilumab + Capecitabine in Stage I-II Triple Negative BRC w/ High-Risk Residual Disease (EMPOWER). TM: K. Arieli

1B-23-4 Ph3 Rand. Study of Giredestrant Compared w/ Fulvestrant, Both Combined w/ CDK4/6i in Pts w/ Estrogen Receptor Positive, HER2-, Adv. Breast Cx w/ Resistance to Prior Adjv. Endocrine Tx. TM: K. Arieli / Massopust (NPB) / Choi (KT)

1B-23-5 Open-Label, Rand/ Ph 3 PF-07220060 + Fulvestrant vs. Investigator's Choice in HR+, Her2- Advanced/Metastatic Breast Cancer. TM: K. Arieli

CTSU-A011801 CompassHER2 Residual Disease (RD), Double-Blind Ph3 Rand. Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib. TM: K. Arieli / Massopust (NB)

CTSU-A211801 Rand., Double-Blind, Placebo-Controlled, Multi-Center, International Ph3 Study to Determine Preventative Effect of Denosumab on Breast Cancer in Women Carrying a BRCA1 Germline Mutation. TM: K. Arieli.

* **CTSU-CCTG MA.39** Regional RT in Biomarker Low Risk Node + Breast Ca. TM: K. Arieli

CTSU-EA1151 Tomosynthesis Mammographic Imaging Screening Trial (TIMIST). TM: K. Arieli.

CTSU-EA1211 Interim FDG-PET/CT For Predicting Response of HER2+ Breast Cx to Neoadj. Tx (DIRECT Trial). TM: K. Arieli

SWOG-S1501 (SUSPENDED) PhIII Carvedilol in prev of cardiac tox in Met HER-2+ BC. TM: K. Arieli

* **SWOG-S1706** Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy Versus Radiotherapy Alone for Inflammatory Breast Cancer. TM: K. Arieli

* **NRG-BR007** Ph3 Trial Evaluation De-Escalation of Breast Radiation for Conservative Tx of Stage 1, Hormone Sensitive, HER2-, Oncotype Recurrence Score Less than or Equal to 18 Breast Cx (DEBRA). TM: K. Arieli

NRG-BR008 Ph3 Rand. Trial of RadioTx Optimization for Low-Risk HER2-Positive Breast Cancer (HERO*). TM: K. Arieli

NRG-BR009 Ph III, Addition of ACT to OFS + ET in Premenopausal Patients w/ pN0-1, ER+/HER2- BC & Oncotype RS = 25. TM: K. Arieli; B. Choi (KT), K. Massopust (NPB)

CNS Tumors

6CNS-07-1 CNS & Spine Tumor Bank. TM: S. Leong

* **6G-15-2** Ph1/2a NEO100 in Recurrent Gr IV Glioma. TM: A. Lozada

6G-22-2 Feasibility Study of Resection + Gammatile Followed by Concomitant EBRT + TMZ and Adjuvant TMZ in Newly Dx'ed GBM. TM: A. Lozada

* **6G-22-4 (SUSPENDED)** Ph1/Rand. Ph2 Trial of Selinexor + TMZ in Recurrent Glioblastoma. TM: A. Lozada

6G-23-1 Ph2b Trial of TVI-Brain-1 Combined w/ Conformal Radiotx + TMZ Compared to SOC as Tx for Newly Diagnosed O6-MGMT Unmethylated GrIV Astrocytoma (GBM). TM: S. Tran

* **6M-22-1** Ph2 Study of Neo100 in Pts. w/ Residual, Progressive or Recurrent High-grade Meningioma. TM: A. Lozada

NRG-BN003 Ph3 Observation vs Irradtx in Gr II Meningioma. TM: A. Lozada

* **NRG-BN010** Safety Run-In and Ph2 Study of Tumor Microenvironment of the Combo of Tocilizumab, Atezolizumab, and Fractionated SRS in Recurrent GBM. TM: A. Lozada

GI

0S-99-10 Blood Collection in GI Cancer. TM: C. Ketchens

3G-07-3 Cell Lines/Xenografts – Adult Solid Tumors & Inflammatory bowel dz. TM: C. Ketchens

* **3G-21-1** Ph2 Rand. Study of Ramucirumab plus Trifluridine/Tipiracil (TAS-102) for Pts with Previously Treated Advanced Gastric or GEJ Adenocarcinoma. TM: C. Ketchens

* **3G-21-2** Open-Label, Ph1b Study of IDX-1197 in Combo w/ Xelox or Irinotecan in Pts. w/ Adv. Gastric Cancer. TM: C. Ketchens

* **3G-22-1** Ph2 Trial of Combination Therapies in Pts. w/ Adv. Upper GI Tract Malignancies (EDGE-Gastric). TM: C. Ketchens / Massopust (NPB) / Choi (KT)

GI – Bile Duct

GI – Esophagus

3E-17-2 (SUSPENDED) Rand Ph2 Pembrolizumab+ Chemotherapy + Chemoradiation in Esophageal Adenocarcinoma. TM: C. Ketchens

* **CTSU-EA2174 (SUSPENDED)** Ph 2/3 Peri-operative Nivolumab + Ipilimumab in Locoregional Esophageal & Gastroesophageal Junction Adenocarcinoma

GI - Colorectal

* **3C-20-6** Ph3 1st line encorafenib + cetuximab +/- chemotherapy vs SOC in BRAFV600E-mutant mCRC. TM: C. Ketchens

3C-21-2 Ph1/1b Study of Targeted Therapies in Subpopulations of Pts. w/ Metastatic CRC (INTRINSIC). TM: C. Ketchens

3C-22-1 (SUSPENDED) Ph 2/3, Rand/Open-Label Maintenance GRT-C901/GRT-R902 + Immune Checkpoint Blockade for Metastatic CRC. TM: C. Ketchens

3C-22-2 Ph2 Rand. Study of Encorafenib + Cetuximab + Pembro vs Pembro Alone in Pts. w/ Prev. Untx'ed BRAF V600-eMutant, MSI-H/dMMR Met. CRC (SEAMARK). TM: C. Ketchens

* **3C-22-5 (SUSPENDED)** Ph1b/2, Open-Label Study of Amivantamab Monotx and in Addition to SOC Chemotx in Pts w/ Adv. or mCRC. TM: C. Ketchens

3C-22-8 Ph1b/2 Rand. Open-Label Study of LBL-007 + Tislelizumab in Combo w/ Bevacizumab + Capecitabine vs Capecitabine as Maintenance Tx in Pts w/ Unresectable or Metastatic Microsatellite Stable / Mismatch Repair Proficient CRC. TM: C. Ketchens / KT (Choi)

3C-23-1 Ph1 Study of TAK-676 as Single Agent and in Combo w/ Pembro in Adults w Adv. Or Metastatic Solid Tumors. TM: C. Ketchens

* **3C-23-2** A Longitudinal Cohort for Locally Adv. CRC. TM: C. Ketchens

3C-23-4 (SUSPENDED) Ph1b Study of OxPhos Inhibitor ME-344 Combined w/ Bevacizumab in Prev. Tx'ed mCRC. TM: C. Ketchens

3C-23-5 Ph3 Open-Label Rand. Study of Tucatinib in Combo w/ Trastuzumab + mFOLFOX6 vs mFOLFOX6 w/ or w/o Cetuximab or Bevacizumab as 1L Tx for Subjs. w/ HER2+ mCRC. TM: C. Ketchens / Massopust (NPB) / Choi (KT)

3C-23-6 Ph1/2 Study of Nons-209 Genetic Vaccine for Tx of Microsatellite Unstable Solid Tx. TM: C. Ketchens / Massopust (NPB)

3C-23-8 Ph1a/1b Study of IGM-8444 as Single Agent and in Combo w/ Subjs w/ Relapsed, Refractory or Newly Diagnosed Cancers. TM: C. Ketchens

3C-23-9 Ph1/2 Study of ZN-c3 Administered in Combo w/ Encorafenib & Cetuximab in Adults w/ mCRC. TM: C. Ketchens / Massopust (NPB)

3C-23-10 Ph2 Rand. Study of Onvansertib in Combo w/ FOLFIRI + Bev or FOLFOX + Bev vs FOLFIRI + Bev or FOLFOX + Bev for 1L Tx of mCRC in Pts w/ KRAS or NRAS Mutation. TM: C. Ketchens / Massopust (NPB) / Choi (KT)

CTSU-EA2201 (SUSPENDED) Ph2 Study of Neoadjv. Nivo + Ipi and Short-Course Radiation in MSI-H/dMMR Locally Adv. Rectal Adenocarcinoma. TM: C. Ketchens

* **NRG-GI008** Colon Adjuvant Chemotx Based on Evaluation of Residual Disease (CIRCULATE-US). TM: C. Ketchens / Massopust (NPB) / Choi (KT)

GI – Anus

* **CTSU-EA2176** Ph3 Rand. Study of Immune Checkpoint Inhibitors with Chemo-tx in Tx-Naïve Metastatic Anal Cancer Pts. TM: C. Ketchens

GI - Liver

3L-17-4 (SUSPENDED) 5-year Longitudinal Observational Study of Natural History / Management of Pts w/ HCC. TM: C. Ketchens

***3L-22-1 (SUSPENDED)** Ph 1/2 Double-Blind/Rand/ Nivo + Relatlimab + Bevacizumab in Adv/Metastatic HCC. TM: Ketchens

3L-22-2 (SUSPENDED) Ph2 Safety, Efficacy of Mt-Ceppa in Combo w/ Sorafenib or Sorafenib Alone, in Tki Naïve Pts with Prev. Tx'ed Adv. HCC and Hep B/C (Outreach2). TM : C. Ketchens

3L-23-1 Ph 1b/2, Open-label, Safety & Efficacy of TTI-101 as Monotherapy and in Combination in Locally Advanced or Metastatic, and Unresectable HCC. TM: C.Ketchens

3L-23-2 Ph1b/2 Rand. Study of Neoadj. Immunotx Combinations in Pts w/ Surgically Resectable HCC (MORPHEUS-NEO HCC). TM: C. Ketchens

3L-23-3 Ph3 Rand. Double-Blind Study of Atezo + Bevacizumab w/ or w/o Tiragolumab in Pts w/ Untx'ed Locally Adv. or Metastatic HCC. TM: C. Ketchens / Massopust (NPB) / Choi (KT)

3L-23-4 Ph II, Open-Label, Multi-Cohort, in Unresectable HCC and Child-Pugh B7 and B8 Cirrhosis. TM: C.Ketchens/ Massopust (NPB)/ Choi (KT)

GI – Gallbladder/Biliary Tract

3BD-23-1 Ph2/3 Study of CTX-009 in Combo w/ Paclitaxel vs Paclitaxel Alone in Adult Pts w/ Unresectable Adv., Metastatic or Recurrent BTCs who have received 1 Prior Systemic Chemotx Regimen. TM: C. Ketchens / Massopust (NPB)

3BD-23-2 Ph1b/2a Study of GNS561 in Combo w/ Trametinib in Adv. KRAS Mutated Cholangiocarcinoma. TM: C. Ketchens

GI – Pancreas

3P-23-1 Rand. Open-Label Ph2 Trial of Nab-paclitaxel + Gemcitabine w/ or w/out Botensilimab (AGEN1811) in Pts w/ Metastatic Pancreatic Cancer who have Progressed on Prior FOLFIRINOX. TM: C. Ketchens / Massopust (NB) / Choi (KT)

3P-23-2 (SUSPENDED) Ph1 Olaparib in Combo w/ Durvalumab (MEDI4736) and Concurrent Radiation Tx Following 1L Chemotx in Locally Adv. Unresectable Pancreatic Cancer. TM: C. Ketchens

3P-23-3 Ph1b Study of ATP150/ATP152, VSV-GP154 and Ezabenlimab (BI 754091) in Pts w/ KRAS G12D/G12V Mutated Pancreatic Ductal Adenocarcinoma. TM: C. Ketchens

3P-23-5 Pancreatic Resection Outcomes in Locally Adv. Pancreatic Cancer Involving Visceral Arteries Treated w/ Neoadj. Chemotx (PROACTIVE Pilot Study). TM: C. Ketchens

3P-23-6 Ph2 Rand. Study of Adjv. Autogene Cevumaran + Atezo + mFOLFIRINOX vs mFOLFIRINOX alone in Pts w/ Resected Pancreatic Ductal Adenocarcinoma. TM: C. Ketchens / Massopust (NPB)

*** SWOG-S2104** Rand/Ph 2 Postoperative Adj. Capecitabine + Temozolomide vs. Observation in High-Risk Pancreatic Neuroendocrine Tumors. TM: C. Ketchens / Massopust (NPB)

GI - Rectal

*** CTSU-A022104** Janus Rectal Cancer Trial: Rand. Ph2 Trial Testing Triplet vs Doublet Chemotx to Achieve Clinical CR in Pts w/ Locally Adv. Rectal Cancer. TM: C. Ketchens.

GI – Stomach

GU - Multiple Sites

GU - Genitourinary

CTSU-A031702 Ph2 Ipilimumab, Cabozantinib & Nivolumab in Rare Genitourinary Cancers (ICONIC). TM: X. Menendez (INTERIM)

4K-23-1 HistoSonics Edison System for Tx of Primary Solid Renal Tumors Using Histotripsy. TM: X. Menendez (INTERIM)

GU – Bladder

4B-13-1 Cystoscopy Registry: Bladder. TM: X.Menendez

*** 4B-15-11 (Neoadjuvant Cohort C)** PII of sEphB4-HAS+ Pembrolizumab MK-7435. TM: X. Menendez (INTERIM) / Massopust (NPB) / Choi (KT)

4B-21-1 Ph 3, Rand. Efficacy of TAR-200 + Cetrelimab vs Concurrent ChemoRT in Participants with MIBC of Bladder not Receiving Radical Cystectomy. TM: X. Menendez (INTERIM)

4B-21-3 Ph3 study of Tookad (padeliporfin) Vascular Targeted Photodynamic Tx for Low Grade Upper Tract Urothelial Cancer. TM: X. Menendez (INTERIM)

4B-21-5 Robotic vascularized composite bladder allograft transplantation: a Phase 0 (first-in-human), single institutional study for deceased donor bladder transplantation. TM: X. Menendez (INTERIM)

4B-22-2 (Cohort 2 Suspended) Ph1a/b Study of TARA-002 in Adults w/ High-grade Non-muscle Invasive Bladder Cancer. TM: X. Menendez (INTERIM)

4B-22-3 Ph1b Erdafitinib Combo w/ Enfortumab Vedotin Following Platinum and PD1/L1 Inhibitors for Metastatic Urothelial Carcinoma w/ FGFR2/3 Genetic Alterations. TM: X. Menendez (INTERIM)

4B-22-4 Ph 1a/b Dose Finding, Open-label, Safety & Toxicity of Intravesical Instillation of TARA-002 in High-grade NMIBC. TM: X.Menendez

4B-22-5 Ph I Erdafitinib Intravesical Delivery (TAR-210) in NMIBC or MIBC & Selected FGFR Mutations or Fusions. TM: X.Menendez

4B-23-1 ADSTILADRIN Early Utilization and Outcomes in the Real World Setting in the U.S. TM: X. Menendez

SWOG-S1937 Ph 3 Randomized Eribulin +/- .Gemcitabine vs SOC Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy. TM: X. Menendez (INTERIM) / K. Massopust (NB)

CTSU-EA8212 Ph3 Trial of Intravesical BCG vs Intravesical Docetaxel + Gemcitabine in BCG Naïve High Grade Non-Muscle Invasive Bladder Cx (BRIDGE). TM: X. Menendez (INTERIM)

GU - Adrenals

GU - Renal

SWOG-S1931 Ph3 Immunotherapy-Based Combo Therapy with/without Cytoreductive Nephrectomy for Met RCC (PROBE). TM: X. Menendez (INTERIM) / Massopust (NB)

GU - Penis

CTSU-A031702 (Cohort E) Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC). TM: X. Menendez (INTERIM)

*** CTSU-EA8134** Int'l Penile Advanced Cancer Trial (InPact). TM: X. Menendez (INTERIM)

GU - Prostate

*** 4B-15-11 (Cohort D)** PII of sEphB4-HAS+ Pembrolizumab MK-7435. TM: X. Menendez (INTERIM) / Massopust (NPB) / Choi (KT)

4P-11-4 CTC Assessment: Prostate. TM: X. Menendez (INTERIM) / O. Castellanos (Westside)

4P-17-3 TRITON3, Ph3 Rucaparib vs Physician's Choice in mCRPC. TM: X. Menendez (INTERIM) / O. Castellanos (Westside)

4P-17-4 Prostate Biomarkers for Repeat Bx. Ileana Aldana

4P-17-8 Metabolic profiling of PBMCs By LC-MS in prostate cancer. TM: X. Menendez (INTERIM) / O. Castellanos (Westside)

4P-18-2 SIMCAP (Surgery in Metastatic Carcinoma of Prostate.TM: X. Menendez (INTERIM)

4P-20-4 (SUSPENDED) PhII-199: PhI/Rand Ph 2Radium-223 Dichloride, M3814, & Avelumab in Advanced mCRPC. TM: X. Menendez (INTERIM)

4P-21-1 Ph3 Rand. Trial: Effect of Vesicopexy on Urinary Continence and QOL Following Robotic-Assisted Radical Prostatectomy. TM: X. Menendez (INTERIM)

4P-21-2 Study of Bioactivity of Low Dose Apalutamide in Prostate Cancer Patients Scheduled for Prostatectomy. TM: X. Menendez (INTERIM)

4P-22-1 Stockholm3 Validation Study in a Multi-Ethnic Cohort for Prostate Cancer (SEPTA). TM: X. Menendez (INTERIM)

***4P-22-2** Longitudinal Advanced Prostate Cancer Cohort (LAPCC). TM: X.Menendez

4P-23-1 PRAMA MRI/Ultrasound fusion guided Transperineal TMA for PCa. TM: X.Menendez

4P-23-3 International, Prospective Open-label, Rand. Ph3 Study Comparing 177Lu-PSMA-617 in combo w/ SOC vs SOC Alone in Adult Male Pts. w/ mHSPC. TM: X. Menendez (INTERIM)

4P-23-5 Prospective, Multicenter, Single-Arm Study of Vanquish Water Vapor Ablation for Prostate Cx. TM: X. Menendez (INTERIM)

4P-23-6 Ph2 Study of Lutetium LU 177 Dotatate in Metastatic Prostate Cx w/ Neuroendocrine Differentiation. TM: X. Menendez (INTERIM)

4P-23-9 Prostate Cancer Tx w/ AquaBeam Robotic System. TM: X. Menendez (INTERIM)

CTSU-EA8191 Ph III, Local or Systemic Therapy Intensification Directed by PET in PC Pts w/ Post-Prostatectomy Biochemical Recurrence [INDICATE]. TM: C.Duran

*** NRG-GU008** Ph 3/Rand Abiraterone Acetate +Prednisone +Apalutamide and Advanced Imaging Into Salvage Treatment Node +ve Prostate Cancer After Radical Prostatectomy. TM: X. Menendez (INTERIM)

* **NRG-GU010** Ph3 Rand/Genomic-Risk Stratified UIR Prostate Cancer: De-Intensification & Intensification Evaluation. TM: X. Menendez (INTERIM)
 * **NRG-GU011** Ph2 Double-Blinded, Placebo-Controlled, RT +/- ADT in Oligometastatic Prostate Cancer (NRG Promethean). TM: X. Menendez (INTERIM)
 * **SWOG-S1802** Ph3and SSTvs SST+ (surgery or Radiation) in mProstate Cancer. TM: X. Menendez (INTERIM)

GU - Testes

4T-22-2 (SUSPENDED) Ph2 Trial of serum Micro RN-371 in Detecting Active Germ Cell Tumors in Pts w/ Suspected Regional Dx. TM: C. Kefauver
 * **CTSU-AGCT1532** PH3 Rand accel vs stand BEPchemo in met.GERMCELL. TM: X. Menendez (INTERIM) / K. Massopust (NB)
SWOG-S1823 Assess miRNA 371 For Outcome in Germ Cell Tumors. TM: X. Menendez (INTERIM)

GYN

* **5GYN-10-3** Tissue Banking - Gyne Surgeries. TM: K. Arieli
 * **5GYN-23-2** Ph1b/2 Basket Study of ACR-368 as Monotx and in Combo w/ Gemcitabine in Adults w/ Platinum Resistant Ovarian Carcinoma, Endometrial Adenocarcinoma and Urothelial Carcinoma Based on Acrivon OncoSignature Status. TM: K. Arieli
NRG-GY020 Ph3 Rand. Trial of Radiation +/- Pembro for New Dx Early-Stage High Intermediate Risk dMMR Endometrioid Endometrial Cancer. TM: K. Arieli

GYN - Cervix

GYN - Ovary

* **NRG-CC008** Non-Rand. Trial Comparing Salpingectomy to Salpingo-Oophorectomy to Reduce Ovarian Cancer Risk Among BRCA1 Carriers (SOROCK). TM: K. Arieli

GYN - Uterus

Head and Neck

0S-23-1 Ph1/2 Study of ZEN0003694 in Combo w/ Etoposide/Platinum in Pts w/ NUT Carcinoma. TM: S. Tran
7H-20-1 AIM-HN and SEQ-HN Study: Tipifarnib in Patients with HNSCC with HRAS Mutations (AIM-HN) and the Impact of HRAS Mutations on Response to 1L Systemic Therapies for HNSCC (SEQ-HN). TM: S. Tran / Massopust (NB)
7H-21-2 Ph2 Rand. Double-Blind, Placebo-Controlled Trial of MIT-001 in Prevention of Oral Mucositis in Patients Receiving Concurrent ChemoRT for Previously Untreated Locally Advanced HNSCC. TM: S. Tran
7H-22-2 Ph2 Open Label Single Arm Study of Pembro for Leukoplakia. TM: S. Tran
 * **7H-22-3** Ph2 Ipatasertib in Combo w/ Pembro for 1L Tx of Recurrent or Metastatic HNSCC. TM: S. Tran
 * **7H-23-1** Ph2 Study of Darolutamide in Combo w/ Leuprolide Acetate in Hormone-Tx Naïve Recurrent and/or Metastatic Androgen Receptor (AR) Positive Salivary Gland Cancer. TM: S. Tran

7H-23-3 Phase 1/2, Escalation & Expansion, MCLA-158 in advanced solid tumors.TM: S.Tran
7H-23-4 Multi-omic Characterization of Head and Neck Carcinogenesis. TM: S.Tran
7H-23-5 A Window of Opportunity Study of Taxanes in HN Cancer. TM: S.Tran
CTSU-A092105 Rand. Ph2 Study of Nivo + Ipi w/ or w/o Cabozantinib in Pts w/ Adv. Nasopharyngeal Carcinoma that have Progressed after Platinum Tx and Immunotx. TM: S. Tran / Massopust (NPB) / Choi (KT)
NRG-HN011 Rand. Ph2 Study of Nivo vs Nivo + Relatimab as Maintenance Tx After 1L Tx w/ Plat-Gem-Nivo for Pts w/ EBV-Associated Recurrent/Metastatic Nasopharyngeal Carcinoma (REMAIN). TM: S. Tran / Massopust (NPB) / Choi (KT)

Lung

Small Cell Lung

20-22-1 Ph1b Study of 1L Tarlatamab in Combo w/ Carboplatin, Etoposide and PDL1 Inhibitor in Subjects w/ Extensive Stage Small Cell Lung Cancer. TM: S. Tran
 * **20-22-3** Ph1 Study of Tazemetostat in Combo w/ Topotecan & Pembo in Recurrent SCLC. TM: S. Tran
20-23-1Rand/ Double-Blind, Placebo-Controlled, Ph III Toripalimab +/- Tifcemalimab (JS004/TAB004) as Consolidation Therapy in Patients With LS-SCLC. TM:S.Tran
 * **NRG-CC009** Ph3.Trial of SRS vs HA-WBRT for 10 or Fewer Brain Mets from SCLC. TM: S. Tran
 * **SWOG-S1827** MRI Brain Surveillance Alone Vs MRI Surveillance +PCI Ph3 in SCLC. TM: S. Tran

Non-Small Cell Lung

2N-19-3 Establishing a Diagnosis of Lung Cancer Through a Fluid Biopsy. TM: S.Tran
2N-21-5 PhI-113/NCI 10327: Ph 1 MLN0128 (sapanisertib) & CB-839 HCl (telaglenastat) in Advanced NSCLC. TM:S.Tran
 * **2N-21-9** Ph2 SubQ Atezo in NSCLC Pts Using a Decentralized Clinical Trial Model. TM: S. Tran
2N-20-1 ALCMI-004 Epidemiology of Young Lung Cancer. TM: S. Tran
2N-20-5 Ph 2 Autologous Tumor Infiltrating Lymphocytes (LN-145) in Metastatic Non-Small-Cell Lung Cancer. TM: S. Tran
2N-20-6 Phase 1/1b S Safety + PK of JNJ-73841937 + JNJ-61186372 in advanced NSCLC. TM: S. Tran
2N-22-1 Ph2 Study of Tiletrectinib in Pts with Adv/Metastatic ROS1+ NSCLC and Other Solid Tumors. TM: S. Tran / Massopust (NB) / Choi (KT)
2N-23-3 Rand, Ph3 Study of AK112 or Placebo Combined w/ Pemetrexed and Carboplatin in Pts w/ EGFR mutant, Locally Adv. Or Metastatic Non-Squamous NSCLC Who Have Failed EGFR-TKI Tx (HARMONi). TM: S. Tran / Massopust (NB) / Choi (KT)
2N-23-4 Ph2 Rand. Trial of PULSAR-Integrated Radiotx + Pembro or Nivo Administered w/ or w/o STING-Agonist IMSA101 in Pts w/ Oligoprogressive Solid Tx. Malignancies. TM: S. Tran
2N-23-5 Ph3 Rand. Study of Ivonescimab Combined w/ Chemotx vs Pembro Combined w/ Chemotx for 1L Tx of

Metastatic Squamous NSCLC (HARMONi-3). TM: S. Tran / Massopust (NPB) / Choi (KT)
2N-23-6 Ph2 Trial of LP-300 in Combo w/ Carboplatin & Pemetrexed in Never Smoker Pts w/ Relapsed, Adv. Primary Adenocarcinoma of Lung After Tx w/ TKIs. TM: S. Tran
 2N-24-1 Ph 2, rand/ enhanced vs. standard derm. management on selected dermatologic AEs in locally advanced or metastatic EGFR-mutated NSCLC. TM: S.Tran/ K.Massopust (NPB); B.Choi (KT)
CTSU-E4512 Ph3 Crizo vs Plac NSCLC. TM: S. Tran
NRG-LU008 Ph III, Rand/ Primary Lung Tumor SBRT + Concurrent Mediastinal Chemoradiation for Locally-Advanced NSCLC. TM: S.Tran
SWOG-S1914 Ph III Induction/Consolidation Atezolizumab + SBRT vs. SBRT Alone in High Risk, Early-Stage NSCLC. TM: S. Tran
SWOG-S2302 Rand/ Ramucirumab + Pembrolizumab vs SOC, Previously Treated w/ Immunotherapy for Stage IV or Recurrent NSCLC. TM: S.Tran; B.Choi (KT), K.Massopust (NPB)

Melanoma

10M-20-1 7T MRI for Early Diagnosis of Melanoma Brain Metastases. TM: S. Tran
10M-23-2 Ph3 Rand. Open-label Study of liuleucel (LN-144) Regimen in Combo w/ Pembro vs Pembro Monotx in Pts w/ Untreated, Unresectable or Metastatic Melanoma. TM: S. Tran
10M-23-4 Ph 1/2, Open-Label/ Safety and Efficacy of OBX-115 in Metastatic Melanoma Resistant to Immune Checkpoint Inhibitors. TM: S.Tran
10M-24-2 Ph1/2 Study of Nivo + Ipi in Combo w/ Sirolimus + Prednisone in Kidney Transplant Recipients w/ Selected Unresectable or Metastatic Cutaneous Cancers. TM: S. Tran / Choi (KT)
 * **CTSU-A091903** Rand. Double-Blind Ph2 Trial of Adj. Nivo w/ or w/o Cabozantinib in Pts. w/ Resected Mucosal Melanoma. TM: S. Tran
CTSU-EA6174 (SUSPENDED) Ph3 comparing MK-3475 (Pembrolizumab) to SOC in Merkel Cell Carcinoma. TM: S. Tran

Sarcoma

11S-20-1 (SUSPENDED) Ph2 Study of Belinostat and Guadecitabine or ASTX727 for Tx of Unresectable and Metastatic Conventional CS. TM: S. Tran / Massopust (NB)
11S-22-1 Ph2 Rand. Study of Atezo w/ or w/o Selinexor in Alveolar Soft Part Sarcoma (AXIOM). TM: S. Tran
 ***11S-23-1 (SUSPENDED)** Rand. Ph2 Study of Cabozantinib, Iplumab and Nivolumab in Pts w/ Soft Tissue Sarcoma. TM: S. Tran / Massopust (NPB) / Choi (KT)

Mesothelioma

Skin

* **14SK-19-1** A PD-1 Checkpoint Inhibitor (Cemiplimab) for High-Risk Localized, Locally Recurrent, or Regionally Advanced Skin Cancer. TM: C. Ketchens / Massopust (NPB) / Choi (KT)

* **14SK-20-1** Rand/ Double-Blind Adj Cemiplimab vs Placebo after Surgery & Radiation in High Risk CSCC Carcinoma. TM: C. Ketchens / Massopust (NPB)

* **14SK-22-1** FIH Ph1/1b Open-Label Study of Bifunctional EGFR/TGF β Fusion Protein BCA101 Monotx and in Combo w/ Tx in Pts w/ EGFR-Driven Adv. Solid Tumors. TM: C. Ketchens.

14SK-24-1 Rand. Ph2 Study of ATR Inhibition in Adv. PDL1 Refractory Merkel Cell Carcinoma (MARTiX Trial). TM: S. Tran / Massopust (NPB) / Choi (KT)

Multiple Sites or Special Studies

* **0S-04-7** USC Tumor &Tissue Bank.

0S-11-5 Circulating Tumor Cell Collection. TM: C. Ketchens

0S-12-3 (SUSPENDED)18F-FMAU Imaging in Ca Pts. B. Desai

0S-12-4 Cancer Genetics Registry. Ricker

0S-15-12 Norris ORIEN Total Cancer Care. Church

0S-17-10 Effects of VR on pain and anxiety in cancer patients undergoing painful procedures. PI: Jacek Pinski, MD

0S-18-8 Precision Performance Status Assessment in Early Phase Clinical Trials. RC: A. Zeng

0S-20-10 Social Health, Activity Behaviors and QOL among Young Adult Cancer Survivors. PI: Kimberly Miller, MD

0S-22-6 Precision Performance Status Correlation to ECOG Performance Status. PI: Jorge Nieva, MD

0S-22-7 Novel Circulating Markers for Monitoring Response to Anti-Cancer Therapy. TM: S. Tran

0S-23-2 Can Narrative Medicine Methods Improve Well-being in Pts w/ GI Malignancies? PI: Eve Makoff, MD

* **3C-21-3** USC Center for Optimization of Pt. Engagement for Cancer Characterization (COPECC). RC: Serina Ovalle.