

Setting	NSCLC (resectable)	NSCLC (unresectable)	NSCLC (metastatic) 1 st Line	NSCLC (metastatic) 2 nd Line +	ES-SCLC/Neuroendocrine
Studies	<p>LCCC 2113 <i>Durvalumab + platinum doublet chemotherapy and ABequolixron (RGX-104) in NSCLC</i> Weiss/Rebecca Rambharose</p>	<p>NRG-LU008 Phase III Randomized Trial of Primary Lung Tumor SBRT Followed by Concurrent Mediastinal Chemoradiation for Locally Advanced NSCLC Weiner/Jordan Hairston</p> <p><i>NBTX stage 3 unresectable NSCLC (Rad Onc Pod)</i> Weiner</p>	<p>HARMONI-3 Randomized, Phase 3 of Ivonescimab (PD-1/VEGF) versus Pembrolizumab + Chemotherapy in First Line, Metastatic Squamous NSCLC Weiss/Rebecca Rambharose</p> <p>BDTX-1535 Oral EGFR inhibitor for uncommon EGFR mutations Patel/Jordan Hairston</p> <p>eVOLVE-01 <i>Volrustomig (PD1/CTLA4 bispecific) Priming Regimens Phase II Study Treatment Naïve non-squamous NSCLC</i> Patel</p> <p>MRTX1719 <i>Patients with Advanced Solid Tumors with Homozygous MTAP Deletion</i> Patel</p> <p>HARMONI-7 <i>Randomized, Phase 3 Study of Ivonescimab Versus Pembrolizumab for the First-line Metastatic NSCLC with High PD-L1 Expression (TPS ≥ 50%)</i> Weiss</p> <p>SUNRAY <i>KRAS G12C-Mutant Metastatic NSCLC Comparing First-Line LY3537982 (KRAS G12C inh) and Pembro vs Placebo and Pembro in PD-L1 ≥50% or LY3537982 and Pembro, Pemetrexed, Platinum vs Placebo and Pembro, Pemetrexed, Platinum all PD-L1</i> Patel</p>	<p>LOXO-RAS-20001 LY3537982 in Patients with KRAS G12C-Mutant Solid Tumors Patel/Jordan Hairston</p> <p>BO45217/KRAScendo-1 Divarasil vs adagrasib/sotorasib for metastatic KRAS G12C-mutant NSCLC Patel/Rebecca Rambharose</p> <p>NBTR3-1100 NBTR3 activated stereotactic radiation in patients with advanced solid tumors Shen/Stephanie Corbett</p> <p>LCCC 2115-ATL CAR-T Cells Expressing GD2 Chimeric Antigen Receptor, IL-15 Weiss/Hannah Ratzlaff</p> <p>IOV-LUN-2022 Autologous Tumor Infiltrating Lymphocytes (LN-145) in NSCLC Weiss/Hannah Ratzlaff</p> <p>EGFR-008 (JANUX) Recombinant Trispecific Ab (EGFR/CD3/Albumin) Weiss/Melissa Flores</p> <p>TSCAN-002 Basket Study Evaluating T-Plex, Autologous Customized T Cell Receptor-Engineered T Cells Targeting Multiple Peptide/HLA Antigens in Participants with Antigen-positive Solid Tumors Weiss/Nazneen Khan</p> <p><i>YL-201</i> <i>B7-H3 ADC for previously treated NSCLC, SCLC, HNSCC, prostate</i> Patel</p> <p><i>RMC6236 vs docetaxel</i> <i>Pan RAS inhibitor</i></p>	<p>LCCC 2117 Lurbinectedin + Trilaciclib (2nd line) Weiss/Jordan Hairston</p> <p>LCCC 2115-ATL CAR-T Cells Expressing GD2 Chimeric Antigen Receptor, IL-15 Weiss/Hannah Ratzlaff</p> <p>PT217X1101 A Phase 1 Study of PT217 (DLL3/CD47 bispecific) in Patients with Advanced Refractory Cancers Expressing DLL3 Weiss/Melissa Flores</p>

Setting	Protocol	Status	Trial Name	PI/SC	Trial Details	Notes/Slots
NSCLC Neoadjuvant Resectable	LCCC 2113	HOLD	Durvalumab + platinum doublet chemotherapy and ABequolixron (RGX-104) in NSCLC	Weiss/ Rebecca Rambharose	-NSCLC, surgical resection standard of care -Stage II-IIIa squamous or non-squamous NSCLC -baseline O2 saturation ≥ 90% at rest/exertion, off supplemental oxygen	
NSCLC Unresectable Chemoradiation	NRG-LU008	OPEN	Phase III Randomized Trial of Primary Lung Tumor SBRT Followed by Concurrent Mediastinal Chemoradiation for Locally Advanced NSCLC	Weiner/ Jordan Hairston	-Stage II or III -Primary tumor <7cm -ECOG PS 0-2 -Known PD-L1 -central tumors excluded	
NSCLC 2 nd Line Metastatic KRAS G12C	LOXO-RAS-20001	OPEN	A Phase 1a/1b Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	Patel/ Jordan Hairston	B1: 2L+ NSCLC (KRAS G12c inhibitor naive) B8: NSCLC KRAS G12Ci (NSCLC with asymptomatic brain metastases) F1: pancreatic cancer KRAS G12Ci	*expanding brain metastases cohort, has intracranial activity
NSCLC 1 st Line Metastatic Squamous	HARMONI-3	OPEN	Randomized, Phase 3 Study of Ivonescimab (PD-1/VEGF bispecific) + Chemo vs Pembro + Chemo for Squamous NSCLC	Weiss/ Rebecca Rambharose	-untreated, metastatic squamous NSCLC (any PD-L1) -asymptomatic, untreated brain metastases allowed (if ≤ 0.5cm) -asymptomatic treated brain metastases allowed (if < 1.5cm) - NO radiographic evidence of major blood vessel encasement - NO arterial thromboembolic event, VTE, CVA, TIA, hypertensive crisis in previous 6 months	
NSCLC 1 st or 2 nd line Metastatic Uncommon EGFR	BDTX-1535	OPEN	Phase 1/2 study to Assess BDTX-1535, on oral EGFR inhibitor, in NSCLC	Patel/ Jordan Hairston	Cohort 3: treatment naive non-classical EGFR inhibitor	*full list of EGFR mutations in protocol. Examples: G719*, L861*, S768I, L718Q, etc
NSCLC 2 nd Line+ Metastatic KRAS G12C	VS-6766-204	OPEN	Phase 1/2 Study of VS-6766 (RAF-MEK Clamp) + Adagrasib KRAS G12C mutant NSCLC	Weiss/ Jordan Hairston	-Requires previous treatment with KRAS G12Ci -No more than 3 prior lines of therapy	
ES-SCLC 2 nd Line +	LCCC 2117	OPEN	Phase II Study of Trilaciclib and Lurbinectidin	Weiss/ Jordan Hairston	-Post platinum-doublet/PD-L1 -Chemotherapy free interval < 90 days -No active/symptomatic brain metastases	
NSCLC 2 nd Line Metastatic KRAS G12C	BO45217	OPEN	Phase III randomized study of divarasib versus sotorasib or adagrasib for previously treated KRAS G12C+ NSLCC	Patel/ Rebecca Rambharose		
MTAP-deleted solid tumors Metastatic	MRTX1719	ACTIVATION	Phase 1/2 Multiple Cohort Trial of MRTX1719 in Patients with Advanced Solid Tumors with Homozygous MTAP Deletion	Patel/ Rebecca Rambharose	-homozygous MTAP deletion -sub-study 1: MRTX1719+pembrolizumab (NSCLC, HNSCC CPS >1, urothelial, esophageal/GE junction CPS >10, MSI-H CRC) -sub-study 2: MRTX1719+carbo/pem+pembro (nsq NSCLC) -sub-study 3: MRTX1719 +gem/abraxane (pancreatic ca) -sub-study 4: MRTX1719+carbo/abraxane+pembro (sq NSCLC)	
Studies Outside of Lung POD						
Setting	Protocol	Status	Trial Name	PI/SC	Trial Details	Notes/Slots
Multiple Solid Tumors 2nd Line +	NBTXR3-1100	OPEN	Phase 1/2 Study of NBTXR3 activated stereotactic radiation in patients with advanced solid tumors	Shen/ Stephanie Corbett	- mets to lung or superficial soft tissues - pretreatment with PD1 acceptable - inoperable NSCLC metastasized to lung, soft tissues, or liver amenable to injection/irradiation.	

NSCLC 2nd Line + Metastatic	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/Olivia Gorman	- no standard of care treatment options <u>Biomarker Cohorts:</u> - 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	
NSCLC Metastatic MET amplification	APL-101-01	OPEN	Phase 1/2 Study of APL-101 in Subjects with Non-Small Cell Lung Cancer with c-Met EXON 14 skip mutations and cMet Dysregulation Advance Solid Tumors	Dees/Elizabeth Schwabe	- C: MET amplification basket tumor types excluding primary CNS tumors - C-1: NSCLC with MET amplification, METi naive - D: c-Met-gene fusion basket type - E: Primary CNS tumors with MET alteration	
NSCLC Later line	EGFR-008 (Janux)	OPEN	Recombinant Trispecific Ab (EGFR/CD3/Albumin)	Weiss/Olivia Gorman		
Metastatic Stage IV NSCLC without EGFR ALK, or ROS1 2nd line +	IOV-LUN-2022	OPEN	A Phase 2 Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Metastatic Non-Small-Cell Lung Cancer.	Weiss/ Hannah Ratzlaff	<u>Inclusion:</u> - 18-70 y.o.; ECOG PS of 0 or 1; life expectancy > 6 months - NSCLC without EGFR, ALK or ROS gene alterations; Stage IV disease - agree to biopsy of measurable lesion and admission of 7 days for administration of lymphodepletion, TILs, and high-dose IL2 <u>Exclusion:</u> - Brain metastases that are clinically threatening - Required use of corticosteroids	
ES-SCLC or Stage IV NSCLC 2nd line +	LCCC 2115-ATL	OPEN	Phase I Study of T Cells Expressing a 2nd Generation GD2 Chimeric Antigen Receptor, IL-15, and iCaspase9 Safety Switch in Subjects with Lung Cancer	Weiss/ Hannah Ratzlaff	<u>Inclusion:</u> - Karnofsky PS of > 60%; life expectancy > or = 12 weeks - ES-SCLC or Stage IV NSCLC; received platinum doublet and PD1 inhibitor; for NSCLC with FDA-approved targeted therapies, must have received such therapies <u>Exclusion:</u> - Required use of corticosteroids - History of allogeneic organ transplant or other cell therapy involving a chemo regimen within last 20 years - Symptomatic, untreated brain metastases	
NSCLC (2 nd line+)	TSCAN	OPEN	Basket Study Evaluating T-Plex, Autologous Customized T Cell Receptor-Engineered T Cells Targeting Multiple Peptide/HLA Antigens in Participants with Antigen-positive Solid Tumors	Weiss/ Nazneen Khan		
TSHS Studies						

Tissue Banking	LCCC 1754	OPEN	UNC Pleural Fluid Registry	Akulian/ Adrianna Warner	- Diagnosed with pleural fluid, are referred for and undergo clinically indicated drainage who have clinical evidence of: a) pulmonary infection (such as fever, leukocytosis, new or worsening infiltrate on chest x-ray, or clinical deterioration) with effusion B) malignancy	Tissue Banking
Tissue Banking	LCCC 2149	OPEN	UNC Lung and Head/Neck Cancer Registry	Akulian/ Adrianna Warner	- Have an appointment at UNC MTOP and/or HNCA pulmonology, ENT, oncology, thoracic surgery, or radiation oncology clinic for the work-up of suspected LHN-CA or management of histologically, cytologically confirmed LHN-CA, or benign lung/head/neck disease. Suspicion of or known LHN-CA (early or metastatic).	Tissue Banking
Tissue Banking	ORACLE	OPEN	Observation of Residual Cancer with Liquid biopsy Evaluation	Patel/ Adrianna Warner	Cohort 2: Non-small cell lung cancer (stage IB-III) -Initial treatment is being given with curative intent -Are planning to undergo regular follow-up and monitoring for cancer recurrence per standard of care	Tissue Banking