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| **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*](mailto:rebecca_rambharose@med.unc.edu?subject=LCCC2113) | *-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 | -StageII or III  -Primary tumor <7cm  -ECOG PS 0-2  -Known PD-L1  -central tumors excluded |  |
| NSCLC  1st 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)  B9: NSCLC KRAS G12Ci + carbo/pem/pembro  F1: pancreatic cancer KRAS G12Ci  G: NSCLC KRAS G12Ci + pembrolizumab (1st line) | \*one cycle of SOC pembro or carbo/pem/pembro allowed prior to enrollment |
| NSCLC  1st 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](mailto:rebecca_rambharose@med.unc.edu?subject=LCCC2113) | -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  1st or 2nd 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 1: non-classical EGFR mutation (up to 2 lines of therapy, 1 EGFR inhibitor)  Cohort 2: C797S EGFR mutation (up to 2 lines of therapy, 1 must be 3rd gen EGFR inhibitor)  Cohort 3: treatment naive non-classical EGFR inhibitor | \*full list of EGFR mutations in protocol. Examples: G719\*, L861\*, S768I, L718Q, etc |
| NSCLC  2nd 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](mailto:Jordan_Hairston@med.unc.edu?subject=VS-6766) | -Requires previous treatment with KRAS G12Ci  -No more than 3 prior lines of therapy |  |
| NSCLC  2nd Line  Metastatic | **S2302**  **(**PRAGMATICA**)** | OPEN | Randomized Study of Ramucirumab + Pembrolizumab versus Standard of Care for Previously Treated with Immunotherapy for Stage IV or Recurrent NSCLC | Lee/[Jasmine Jordan](mailto:jasmine_jordan@med.unc.edu?subject=PRAGMATICA) | -Stage IV or recurrent NSCLC  -Received PD-1/PD-L1 for advanced disease  -Disease progression > 84 days from initiation of anti-PD1/PD-L1  -Received platinum-based chemotherapy |  |
| ES-SCLC  2nd Line + | **LCCC 2117** | OPEN | Phase II Study of Trilaciclib and Lurbinectedin | Weiss/[Jordan Hairston](mailto:Jordan_Hairston@med.unc.edu?subject=LCCC2117) | -Post platinum-doublet/PD-L1  -Chemotherapy free interval < 90 days  -No active/symptomatic brain metastases |  |
| 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  -phase 1b monotherapy expansion (NSCLC)  -substudy 1: MRTX1719+pembrolizumab (NSCLC, HNSCC CPS >1, urothelial, esophageal/GE junction CPS >10, MSI-H CRC  -substudy 2: MRTX1719+carbo/pem+pembro (nsq NSCLC)  -substudy 3: MRTX1719 +gem/abraxane (pancreatic ca)  -substudy 4: MRTX1719+carbo/abraxane+pembro (sq NSCLC) |  |
| NSCLC  2nd Line  Metastatic  KRAS G12C | **BO45217** | ACTIVATION | Phase III randomized study of divarasib versus sotorasib or adagrasib for previously treated KRAS G12C+ NSLCC | Patel/Jordan Hairston |  |  |

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| **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/Melissa Flores | - no standard of care treatment options  Biomarker Cohorts:  - 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 ex 14 deletion or 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/Melissa Flores | - A-1 (NSCLC harboring Exon 14 skipping mutations, untreated)  - A-2 (NSCLC previously treated EXON 14skip mutated, c-Met inhibitor naive)  - 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 | NX-1607-101 | OPEN | Phase 1a, Dose Escalation  Study of NX-1607, a CBL-B inhibitor, in Advanced Malignancies, with Phase 1b Expansion in Select Tumor Types | Weiss/Melissa Flores | - metastatic disease, not candidate for SOC  - NX-1607 monotherapy or NX-1607+paclitaxel |  |
| NSCLC  Later line | EGFR-008 (Janux) | OPEN | Recombinant Trispecific Ab (EGFR/CD3/Albumin) | Weiss/Melissa Flores |  |  |
| Metastatic  HER2 overexpression | CT-0508-101 | OPEN | 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. | Abdou/Catherine Cheng | -fresh biopsy showing HER2 positive |  |
| 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/Catherine Cheng | Inclusion:  - 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 of lymphodepletion, TILs, and high-dose IL2  Exclusion:  - 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/Catherine Cheng | Inclusion:  - Karnofsky PS of > 60%; life expectancy > or = 12 weeks  - ES-SCLC or Stage IV NSCLC; received platinum doublet and PD1 inhibitor; for NCSLC with FDA-approved targeted therapies, must have received such therapies  Exclusion:  - 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 |  |
| **TSHS Studies** | | | | | | |
| Tissue Banking | LCCC 1754 | OPEN | UNC Pleural Fluid Registry | Akulian/[Adrianna Warner](mailto:adrianna_warner@med.unc.edu) | - 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](mailto:adrianna_warner@med.unc.edu) | - 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](mailto:adrianna_warner@med.unc.edu) | 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 |