UCI Chao Family Comprehensive Cancer Center

Lung Clinical Trials

Single Mutation-Driven Trials					
PI	**CRC**	**Protocol # / Title**	**Mutation**	**Primary Inclusion/Exclusion Criteria**	**Status**
Ou	Anabel Serwanska	UCI 16-96: A Phase I Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors	RET rearrangement/fusion or mutation	Cohort 5 must have oncogenic RET rearrangement/fusion or mutation solid tumor. Cohort 5: Solid tumor w/ other RET fusion, prior SOC treatment. All groups must have measureable disease per RECIST v.1.1. Excluded if cancer has known primary driver alteration other than RET (i.e NSCLC with targetable mutation in EGFR,ALK, ROS1, or BRAF; colorectal with oncogenic KRAS, NRAS, or BRAF mutation.	Part 2: Cohort 5 Open (Slot assignment required prior to screening)
Ou	Anabel Serwanska	UCI 18-21: A Phase I/II Study of Oral LOXO-292 in Patients with Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation (LIBRETTO-001)	RET rearrangement or mutation	PART 2: Any patient with RET altered solid tumor (including RET-fusion positive NSCLC or RET-mutant MTC) eligible for Cohort 6. Patients who otherwise are eligible for Cohorts 1-5 who discontinued another RET inhibitor due to intolerance may be eligible with prior Sponsor approval. Cohorts 1 and 3: failed or intolerant to standard of care; Cohorts 2 and 4: without prior standard-first line therapy.	Phase 2: Cohorts 6 Open (Slot assignment required prior to screening)
Ou	Oliver Quines	UCI 19-61 A Phase I/II Study of REGN5039 in Patients with Met-Altered Advanced Non-Small Cell Lung Cancer.	MET exon 14, MET gene amplificiation; elevated MET protein expression	MET-exon14 gene mutation and/or MET gene amplification (MET/CEP7 ratio ≥1.8 or MET GCN ≥4), and/or elevated MET protein expression (IHC ≥2+ or H score of >150). Cohorts 1, 2A, 2B, 2C, and Cohort 3 see inclusion criteria. Exclusion: Currently receiving treatment therapeutic study, or participated in a study of investigational agent or investigational device within 4 weeks of first dose of study therapy.	Dose expansion phase Cohort 1a, 1b, 2a, 2c open; Cohort 2b on hold (Slot assignment required prior to screening)

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Single Mutation-Driven Trials					
Lee	Keagan Buttigieg	UCI 19-57: A Phase I, Open-Label, Multi-Center, First-In-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0022, A Novel Met/CSF1R/SRC Inhibitor, in Patients with Advanced Solid Tumors Harboring Genetic Alterations In Met	MET (TPT)	For dose escalation part: Subjects with histological or cytological confirmation of advanced/metastatic solid tumors harboring the genetic MET alteration(s) including exon 14 deletion (METΔex14), amplification, fusion or activating kinase mutation, who are resistant or intolerant to standard therapy; OR are unlikely to tolerate or derive clinical benefit from standard therapy in the opinion of the Investigator OR have declined standard therapy	Suspended
Ou	Keagan Buttigieg	UCI 19-111 Phase I/II, First-in-Human Study of a Treatment for Patients with Advanced Solid Tumors Harboring Oncogenic Ret Fusions or Mutations	RET(TPT)	INC: Histologically confirmed diagnosis of advanced/metastatic solid tumors harboring oncogenic RET gene fusions or mutations. Exc: Presence of RET Gatekeeper mutation(s). Exposure to more than 1 prior selective RET inhibitor unless discontinued due to intolerance.	Open to Accrual (Slot assignment required prior to screening)
Ou	Gabriela Mamani	UCI 18-78: A Phase I/II Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation	KRAS G12C	Phase 2 Cohort D: Other solid tumors outside of NSCLC/CRC; unresectable or metastatic disease. Phase 1b 1st-line treatment for NSCLC; patients with limited brain metastases; CRC patients for combination with cetuximab. No available treatment or patient declines therapy EXCEPT phase 2, patients must have received at least platinum chemotherapy and checkpoint inhibitor therapy AND no prior treatment with targeted KRAS G12C therapy.	Certain Phase 1b cohorts and Phase 2 Cohort D/E/F. Open to Accrual (Slot assignment required prior to screening)
Ou	Oliver Quines	UCI 19-132: Single-Arm Study of Lorlatinib in Participants with Anaplastic Lymphoma Kinase (ALK)-Positive Non-Small Cell Lung Cancer (NSCLC) Whose Disease Progressed After One Prior Second-Generation ALK Tyrosine Kinase Inhibitor (TKI)	ALK rearrangement	Metastatic NSCLC with disease progression after first-line alectinib or certinib. Prior chemotherapy allowed if done prior to alectinib/certinib. Measurable disease per RECIST 1.1. Asymptomatic CNS metastases OK, including patients on stable or decreasing steroid use.	Open to Accrual
Ou	Oliver Quines	UCI 20-66: Ph II Glutaminase Inhibitor Telaglenastat w/Pembro & Chemo in KEAP1/NRF2-Mutated NSCLC	KEAP1/NRF2	Stage IV disease not previously treated with systemic therapy for metastatic NSCLC. Patients who received adjuvant or neoadjuvant therapy (w/without immunotherapy) for localized NSCLC are eligible if adjuvant/neoadjuvant therapy (including immunotherapy) was completed at least 6 months prior to the development of metastatic disease. No known actionable mutation in EGFR, ALK, ROS1, BRAF, NTRK or other known actionable mutation for which there is approved therapy in the first-line lung cancer setting.	Open to accrual

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Ou	Oliver Quines	UCI 20-05:Ph III Pyrotinib vs Docetaxel Pts w/AdvNSCLC w/HER2Exon 20Mut Progress on/After Tx w/Plat Base Chemo	HER2	INC: Histologically or cytologically confirmed locally advanced (not amenable to curable surgery or radiotherapy) or mets non-squamous NSCLC disease (Stage IIIB – IV). Confirmed presence of activating mutations in exon 20 of the HER2 gene. Provided to retrospectively confirm the mutation status of the HER2 gene. EXC: Previously treated with targeted drugs for HER2 gene mutations (including but not limited to trastuzumab and its conjugated drugs, pertuzumab, lapatinib, pyrotinib, neratinib, afatinib, dacomitinib, poziotinib) and previously treated w/ docetaxel.	Requesting to Abandon/Close study
Ou	Anabel Serwanska	UCI 20-141: Phase I Dose-Escalation and Dose-Expansion Study Evaluating the Safety, Pharmacokinetics, and Activity of GDC-6036 in Patients with Advanced Solid Tumors with a KRAS G12C Mutation	KRAS G12C	KRAS G12C Patients including but not limited to NSCLC/CRC. Measurable or evaluable disease per RECIST 1.1. Fresh or archival tissue required at screening. NSCLC and CRC patients must not have known concomitant second oncogenic drivers. CNS metastases OK if asymptomatic, previously treated, and doesn't require corticosteroid treatment.	Open to Accrual
Ou	Gabriela Mamani	UCI 20-185 A Phase I/IB, Open-Label, Dose Escalation and Expansion Study of SBT6050 Alone and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors Expressing HER2	HER2	Inc:Subjects must have completed treatment with other systemic cancer therapy, including completing mAb-based therapy at least 4 weeks prior to first dose of study treatment, and completing chemotherapy or therapy with small molecules at least 2 weeks prior to first dose of study treatment. Investigational therapies must be completed at least 4 weeks prior to the first dose of study treatment. Local radiation therapy must have been completed at least 2 weeks prior to the first dose of study treatment. Eligible subjects must not be known to have the following tumor characteristics: microsatellite instability high (MSI-H), deficient mismatch repair (dMMR) and/or tumor mutational burden high (TMB-H, ≥10 mutations per megabase).	Open to Accrual
Ou	Celest Ramirez	UCI 20-194: A Phase I/II, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of D-1553 in Subject with Advanced or Metastatic Solid Tumors with KRasG12C Mutation	KRAS G12C	Subject has KRasG12C mutation in tumor tissue or blood, pleural effusion or other samples containing cancer cells or DNA. Historical, local laboratory result (up to 5 years prior to this study) can be used for Phase 1 subjects. Phase 2 subjects must be tested for KRasG12C mutation by a central laboratory. Subject has tumor type requirement as follows: a. Phase 1a: advanced or metastatic solid tumors for which no standard treatment is available or the subject is refractory to or intolerant of existing standard treatment; b. Phase 1b Group 1 and Phase 2 Arm C: advanced or metastatic (NSCLC) with no EGFR or ALK genomic tumor aberrations, indicated for pembrolizumab in combination with pemetrexed and platinum chemotherapy or in combination with carboplatin and either paclitaxel or paclitaxel protein-bound therapy per pembrolizumab prescribing information; c. Phase 1b Group 2 and Phase 2 Arm D: advanced or metastatic (CRC) previously untreated or treated with irinotecan-based therapy and indicated for mFOLFOX 6 or CapeOx treatment, as judged by the investigator;	Open to Accural

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Single Mutation-Driven Trials					
Ou	Oliver Quines	UCI 20-102:A Randomized, Open-Label Phase III Study of Combination JNJ-61186372 and Carboplatin-Pemetrexed Therapy, Compared with Carboplatin-Pemetrexed, in Patients with EGFR Exon 20ins-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer	EGFR EXON 20	Participant must have histologically or cytologically confirmed, locally advanced or metastatic, nonsquamous NSCLC with documented primary EGFR Exon 20ins activating mutation (a copy of the mutation analysis must be submitted during screening) performed by a Clinical Laboratory Improvement Amendments Participant must agree to genetic characterization of tumor status through the required pretreatment tumor biopsy (or submission of equivalent archival material), as well as baseline and periodic blood samples for analysis of tumor mutations in the bloodstream (CLIA)-certified (US sites) or an accredited (outside of the US) local laboratory.	Open to Accrual
Ou	Anabel Serwanska	UCI 20-133: Phase I/II Study of the Selective RET Inhibitor TAS0953/HM06 in Patients with Advanced Solid Tumors with RET Gene Abnormalities	RET Gene Abnormalities	Phase I/II Study of the Selective RET Inhibitor TAS0953/HM06 in Patients with Advanced Solid Tumors with RET Gene Abnormalities (eligibility criteria pending).	Open to Accrual
Ou	Gabriela Mamani	UCI 20-204: A Randomized, Double-Blind, Placebo-Controlled Trial of Tomivosertib in Combination with Anti-PD-(L)1 Therapy in Subjects With Non-Small Cell Lung Cancer as First-Line Therapy or When Progressing on Single-Agent First-Line Anti-PD-(L)1 Therapy	PDL-1	INCLUSION: Cohort A: Have initiated first-line therapy for NSCLC with pembrolizumab, Have tumor PD-L1 ≥50% by 22C3 IHC, judged by PI tolerated pembrolizumab monotherapy and have been on pembrolizumab for at least 3 months. Cohort B: received chemotherapy and/or anti-PD-(L)1 therapy in the neo/adjuvant setting, provided the last dose of therapy was >9 months prior to randomization. EXCLUSION: Have received platinum-based chemotherapy or initiated anti-PD-(L)1 therapy with chemotherapy for locally advanced or metastatic NSCLC	Open to Accural
Lee	Keagan Buttigieg	UCI: 21-30: A Phase I/II Study of TPX-0131, A Novel Oral ALK Tyrosine Kinase Inhibitor in Subjects with ALK+ Advanced or Metastatic NSCLC	ALK	Inclusion: Phase 1 only. Harboring an ALK gene fusion, who have progressed after the most recent line of treatment. Must have been pretreated with up to three prior lines of an ALK TKI treatment, including at least one prior line of a second or third-generation ALK TKI (alectinib, brigatinib, ensartinib, or lorlatinib). Note: subject will not be eligible if he/she has received more than three lines of an ALK TKI.The subject may have been treated with no more than one prior line of chemotherapy AND/OR immunotherapy, before or after ALK TKI treatmen. Phase 2 Expansion: Refer to inclusion criteria for expansion 1-3. EXCLUSION: Known oncogene drivers other than ALK conferring sensitivity to targeted therapies	Open to Accrual
Ou	Anabel Serwanska	UCI 20-68: A Phase II Study of Seribantumab (FTN100) in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors	NRG1	Patients with NRG1 fusion positive locally advanced or metastatic solid tumors as assessed by molecular assays, such as PCR, NGS (RNA or DNA) or FISH testing. Such patients should have received and progressed after a minimum of one prior standard therapy appropriate for their tumor type and stage of disease.	Open to accrual
Ou	Oliver Quines	UCI 21-47: A Phase I/II Study of the Highly Selective ROS1 Inhibitor NUV=520 in Patients with Advanced NSCLC and Other Solid Tumors	ROS1	A Phase I/II Study of the Highly Selective ROS1 Inhibitor NUV=520 in Patients with Advanced NSCLC and Other Solid Tumors	PRMC Approval (Pending Activation)
Ou	TBD	UCI 21-63: A Phase IB/II, Open-Label, Multicenter Study of ERAS-007 in Combination with Other Anti-Cancer Therapies in Patients with Advanced Non-Small-Cell Lung Cancer (HERKULES-2)	EGFR	PhIB/IIERAS007 inCombo w/Osimbertinib inPts w/AdvEGFRm NSCLC WhoProgressed on or After OsimertinibTx	PRMC Approval (Pending Activation)
Ou	Gabriela Mamani	UCI 21-53: A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	KRAS G12-C	A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	Open to Accrual

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Nagasaka	TBD	UCI 21-187: A Phase IB Multicenter, Open-Label Dose-Escalation Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Durvalumab in Combination with Cisplatin, Carboplatin or Pemetrexed in First-Line Treatment of Patients with Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 Overexpression (HER2+) (DESTINY-Lung03)	HER2+	The target population of interest in this study is adult patients with histologically documented non-squamous HER2+ mNSCLC. Part 1 of the study will enroll second- or third-line patients. Part 2 of the study will include treatment-naïve patients only and will exclude tumors with EGFR mutations (eg, exon 19 deletion or exon 21 L858R), EML4-ALK fusion, and/or any other therapy-targetable alteration, if known.	PRMC Approval (Pending Activation)

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Multiple Mutation-Driven Trials					
PI	**CRC**	**Protocol # / Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Ou	Oliver Quines	UCI 20-42: A Phase I, Open-Label, Multi-Center, Dose-Finding, Pharmacokinetic, Safety and Tolerability Study of PF-07265807 in Participants with Selected Advanced or Metastatic Solid Tumor Malignancies	Solid tumor malignancies	Patients wil cervical cancer, gastric cancer, esophageal cancer, endometrial cancer, HCC, melanoma, Merkal cell carcinoma, MSI-H tumors, NSCLC, HNSCC, SCLC, RCC, or urothelial carcinoma for whom no standard therapy is available or patient refused standard therapy. Known symptomatic brain metastases excluded.	Open to Accrual

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Multiple Mutation-Driven Trials					
Lee	Keagan Buttigieg	UCI 16-79: A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients with Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1)	ROS1, NTRK1, NTRK2, NTRK3 rearrangement	**INCLUSION:** Histologically or cytologically confirmed diagnosis of locally advanced or metastatic solid tumor (including non-Hodgkin Lymphoma and primary CNS tumors) that harbor an ALK, ROS1, NTRK1, NTRK2, or NTRK3 gene rearrangement as by any nucleic acid based diagnostic testing, FISH and Immunohistochemistry (IHC). All subjects must have archival tissue sample or de novo sample available and collected prior to enrollment. At least 7 days or 5 half-lives (whichever is shorter) must have elapsed since completion of treatment with the last ALKi, ROS1i, or TRKi prior to starting treatment with TPX-0005 for subjects enrolling into the TKI-refractory expansion cohorts. All side effects from prior treatments with ALKi, ROS1i, and TRKi must have resolved to grade ≤ 1 prior to starting treatment with TPX 0005; however, the most immediate treatment prior to enrollment does not have to be a TKI.Prior ALKi allowed include crizotinib, ceritinib, alectinib, brigatinib, lorlatinib, ensartinib, ASP3026, TSR- 011. Prior ROS1i allowed include crizotinib, ceritinib, lorlatinib, brigatinib, entrectinib, ensartinib, DS6051b, ASP3026, cabozantinib. Prior TRKi allowed include entrectinib, larotrectinib, LOXO-195, DS6051b. Crizotinib is not considered a TRKi for the purpose of this trial. Other prior ALKi, ROS1i, and TRKi not listed above may be allowed after discussion with TP Therapeutics **EXCLUSION:** Symptomatic brain metastases or leptomeningeal involvement.	Phase 2 Open to Accrual
Ou	Oliver Quines	UCI 18-14: A Phase I, Open-Label, Multicenter Dose Escalation Study of RMC-4630 Monotherapy in Adult Patients with Relapsed/Refractory Solid Tumors	Dose Expansion: RTK mutations, amplifications or rearrangements, KRASG12, BRAF Class 3, or NF1 LOF mutations	Advanced solid tumors that failed, intolerant to, or ineligible for standard of care anticancer treatments.	Open to Accrual (Slot assignment required prior to screening)
Ou	Keagan Buttigieg	UCI 19-03: Ph I Study of JNJ-61186372 in Subjects with Non-Small Cell Lung Cancer	EGFR, CMET amplification	Part 1 Chemotherapy Combination Cohort: Subjects must have histologically or cytologically confirmed NSCLC that is metastatic or unresectable and be eligible for treatment with combination carboplatin and pemetrexed, in accordance with standard of care, and be willing to receive additional investigational therapy with JNJ-61186372. for patients who are 800 kg and over. Part 2 Cohort MET-2: Subjects with NSCLC abd documented primary MET exon 14 skipping mutation.	Open Cohort MET -2 with primary MET exon 14 skipping mutation NSCLC (Slot assignment required prior to screening)
Ou	Keagan Buttigieg	UCI 19-64: A Phase I/II Study of MCLA-128, a Full Length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors	HER2, HER3, NRG1	Inc: Patients received prior standard therapy or opinion of the Investigator, unlikely tolerate or derive clinically meaningful benefit from standard of care therapy. Locally-advanced unresectable or metastatic solid tumor malignancy documented NRG1 gene fusion, identified through PCR, next generation sequencing-based assays [DNA or RNA], or FISH performed at CLIA or other similarly-certified laboratories.	Open to Accrual

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Ou	Celest Ramirez	UCI 20-14: A Phase I, Open-Label, Multicenter, Safety Study of SAR442720 in Combination with Pembrolizumab in Patients with Advanced Malignancies	KRAS amplification or mutations of KRASG12, NF1 LOF, or BRAF Class 3 mutations.	Histologically or cytologically proven diagnosis of non-squamous NSCLC w/mets disease progression after platinum based chemo and ICI irrespective sequence. At least one prior line of treatment in metastatic setting.	Dose expansion only accepting treatment naïve NSCLC patients\ (Slot assignment required prior to screening)
Ou	Leo Inocencio	UCI 19-65: A Phase I/II, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Anti-tumor Efficacy of DZD9008 in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) with EGFR or HER2 Mutation	EGFR or HER2	Part A: Patients confirmed locally advanced or metastatic NSCLC with EGFR or HER2 mutations; must have relapsed from, refractory to, or are intolerant to prior standard therapy. Sufficient archival/fresh tumor tissue required at screening. Measurable disease per RECIST 1.1. Brain metastasis OK if stable, asymptomatic, and doesn't require corticosteroid treatment.	Part A food effect open for accrual (Slot assignment required prior to screening)
Ou	Keagan Buttigieg	UCI 19-121: A Phase I/II Open-label, Two-part, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Antitumor Activity of BDTX-189, an Inhibitor of Allosteric ErbB mutations, in Patients with Advanced Solid Malignancies	EGFR or HER2	Part A: Patients with a solid tumor with alterations such as: Allosteric HER2 (see Appendix I) or HER3 mutation(s), EGFR or HER2 exon 20 insertion mutation (see Appendix I), HER2 amplified or overexpressing tumor, EGFR exon 19 deletion or L858R mutation. Part B: Patients with a solid tumor harboring an: Allosteric HER2 mutation, EGFR or HER2 exon 20 insertion mutation as determined by a validated NGS test routinely used by each institution using tissue and/or plasma. Eligible mutations are summarized in Appendix I. Eligible patients will be assigned to one of the 4 following cohorts: 1) NSCLC with EGFR or HER2 exon 20 insertion mutation; 2) Breast cancer with an allosteric ErbB mutation; 3) Any tumor (except breast) with an S310F/Y mutation; 4) Any other allosteric ErbB mutation not assigned to Cohorts 1-3	Open to Accrual (Slot assignment required prior to screening)
Ou	Anabel Serwanska	UCI 20-107: A Phase II Study to Evaluate the Safety and Efficacy of AB122 Monotherapy, AB154 in Combination with AB122, and AB154 in Combination with AB122 and AB928 in Front-Line, Non-Small Cell Lung Cancer	PD-L1	Randomized trial Inclusion: high programmed death ligand 1 (PD-L1) expression (Tumor Proportion Score [TPS] ≥50%). Exclusion: Use of other investigational drugs (drugs not marketed for any indication) within 28 days or 5 half-lives (whichever is longer) of first dose of IP.	Open to Accrual (slot request required)
Ou	Gabriela Mamani	UCI 20-92: A Phase III, Randomized Study of Amivantamb and Lazertinib Combination Therapy Versus Single Agent Osimertinib or Lazertinib as First-Line Treatment in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer	EGFR	**Inclusion# 3**. Participant must have a tumor that was previously determined to have Exon 19del or Exon 21 L858R substitution, as detected by FDA-approved or other validated test in CLIA certified laboratory (sites in the US) or accredited local laboratory (sites outsideof the US). biopsy must have been obtained at or after the diagnosis of advanced disease. (Note: A copy of the test report documenting the EGFR mutation must be included in the participant records and must also be submitted to the sponsor.) **Exclusion# 1:** Participant has received any prior systemic treatment for locally advanced or metastatic disease (adjuvant or neoadjuvant therapy is allowed, if administered more than 12 months prior to the development of locally advanced or metastatic disease).	Open To Accrual

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Ou	Oliver Quines	UCI 20-119: An Open-Label Phase I/Ib Study to Evaluate the Safety and Pharmacokinetics of JNJ-73841937 (Lazertinib), a Third Generation EGFR-TKI, as Monotherapy or in Combinations with JNJ-61186372, a Human Bispecific EGFR and cMet Antibody in Participant	EGFR, EGFR exon 19del or L858R, rare EGFR mutations	Patients must have metastatic/unresectable EGFR-mutated NSCLC. Phase 1/1b combination: EGFR mutated, must have progressed after SOC therapy, exhausted all available options with targeted therapy, or refused all currently available therapies. Lazertinib + Amivantamab + chemo cohort: Must have progressed on or after an EGFR TKI as most recent line of treatment. Maximum 3 prior lines of tx in metastatic setting allowed. Expansion cohort A: EGFR exon 19 del or L858R mutated, progressed on prior treatment with osimertinib and platinum-doublet chemotherapy for metastatic disease. Expansion Cohort B: documented primary EGFR Exon 20ins activating mutation Expansion Cohort C: uncommon non-Exon 20ins activating mutation. May be treatment naive or treated with 1 prior line of tx (must be 1st/2nd gen TKI). Expansion Cohort D: EGFR Exon19 deletion or L858R) that has progressed on prior treatment with osimertinib in 1L/2L as immediate prior line of therapy. Measurable or evaluable disease required (cohort-dependent). Brain mets OK if asymptomatic or doesn't require treatment.	Open to Accrual LACP Cohort closed. Cohorts B, C, D open

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Multiple Mutation-Driven Trials					
Ou	Gabriela Mamani	UCI 20-195: Phase I/II Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-C-MET Bispecific Antibody, in Patients with Advanced NSCLC and Other Solid Tumors	Activating EGFR mutations/amplifications, activating cMET mutation/amplification	Patients who have progressed on SOC treatment or are ineligible for, or have refused all other available therapeutic options. Measurable disease per RECIST. Untreated or symptomatic CNS metastases is excluded.	Open to Accrual (Slot assignment required prior to screening)
Bota	Mehir Tharani	ECOG-EAY131: Molecular Analysis for Therapy Choice (MATCH)	Mutation-specific treatments	Positive for specific mutations.	Open to Accrual
Ou	Oliver Quines	UCI 20-36: A Phase II Randomized Open-Label Study of Patritumab Deruxtecan (U3-1402) in Subjects with Previously Treated Metastatic or Locally Advanced EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)	EGFR activating mutation (exon 19 del or L858R)	At least 1 prior line of EGFR TKI treatment and systemic therapy with at least 1 platinum-based chemo regimen. Archival or fresh biopsy required. No prior treatment with anti-HER3 antibody or single-agent topoisomerase I inhibitor. No prior treatment with ADC consisiting of any topoisomerase I inhibitor. Patients with clinically inactive or treated brain mets who are asymptomatic may be included in the study.	Open to Accrual
Ou	Anabel Serwanska	UCI 21-27: APh I/II Study Targeting Acquired Resistance Mechanisms in Patients with EGFR Mutant NSCLC	EGFR	A Phase I/II Study Targeting Acquired Resistance Mechanisms in Patients with EGFR Mutant Non-Small Cell Lung Cancer	IRB INITIAL APPROVAL
Ou	Keagan Buttigieg	UCI 20-211: A Phase I, Open-Label, Multi-Center, Dose Escalation and Dose Expansion Study to Evaluate the Safety Tolerability, Pharmacokinetics, and Preliminary Evidence of Anti-Tumor Activity of PF-07284892 (Arry-558) as a Single Agent and in Combination Therapy in Participants with Advanced Solid Tumors	ALK +, ROS 1+, BRAF V600, (K, N, H-RAS), NF-1, BRAF class 3.	INCLUSION: Part 1&2 Underwent at least 1 prior standard of care therapy and no approved/alternative therapies are available. ALK-positive participants must have ≥1 prior ALK inhibitor or ≥2 prior ALK inhibitors if prior crizotinib. ROS1-positive participants must have at least 1 prior treatment with crizotinib, entrectinib, and/or ceritinib. EXCLUSION: Systemic anti-cancer therapy or small molecular therapeutic(s) (approved or investigational) within 2 weeks (4 weeks for antibodies, 6 weeks for mitomycin C or nitrosoureas) or 5 half-lives of the agent(s), whichever is shorter, prior to study entry (Day 1)	Open to Accrual (Slot assignment required prior to screening)
Ou	Anabel Serwanska	UCI 21-12: A Phase I/IB, Open-Label, Multicenter, Dose-Escalation Study of RMC-5552 Monotherapy in Adult Subjects with Relapsed/Refractory Solid Tumors	PIK3CA/TSC 1 / 2 / STK11 / MTOR / MYC Amplificaiton	INCLUSION: Dose Expansion Phase at RP2D, subjects must have one of the following molecular aberrations, •Cancers w/ hotspot PIK3CA mutations or phosphatase and tensin homolog (PTEN) loss of function.•Cancers w/ tuberous sclerosis complex subunit 1/2 (TSC1/2) or serine/threonine kinase 11 (STK11) loss of function or MTOR mutations.•Cancers w/ amplification of MYC (MYC proto-oncogene, bHLH transcription factor).•No oncogenic driver co-mutation of mitogen-activated protein kinase (MAPK) pathway. Exclusion: Treatment w/ chemo or TKI within 14 days or 5 half-lives (for nitrosourea and mitomycin C within 6weeks of C1D1 whichever is longer.	Open to Accrual (Slot assignment required prior to screening)

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Non-mutation driven Trials / Correlative					
Dr. O'Brien	Mashal Chotani	NCICOVID: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study	Data, specimen, and image collection	Actively undergoing cancer treatment (chemotherapy, targeted therapy, immunotherapy, and/or radiation therapy) or follow-up care treatment that requires regular visits to UCI Health - Orange or Newport. Must be currently testing for SARS-CoV-2 or has had first positive test < 14 days.	Open to Accrual
Ou	Gabriela Mamani	UCI 20-158: A Phase II Study of Nivolumab Plus Relatlimab in Combination with Chemotherapy vs. Nivolumab in Combination with Chemotherapy as First Line Treatment for Subjects with Stage IV or Recurrent Non-Small Cell Lung Cancer		INCLUSION: Histologically confirmed metastatic NSCLC of squamous (SQ) or non-squamous (NSQ) histology with Stage IV or recurrent disease following multi-modal therapy for locally advanced disease. Tissue Block to cut 20 unstained slides of tumor tissue from core biopsy, punch biopsy, exicisional biopsy or surgical specimen during screening prior to enrollment. EXCLUSION: Participants with EGFR, ALK, or ROS-1 mutations which are sensitive to available targeted inhibitor therapy. All participants with NSQ histology must have been tested for EGFR, ALK, or ROS-1 mutation status. Participants with NSQ histology and unknown EGFR, ALK, or ROS-1 status are excluded.	Part 1 closed to Accrual. Part 2 pending re-opening

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