CLINICAL TRIALS

BREAST

TRIO

Research Study	Indication & Line of Therapy	Intervention	Key Criteria	Protocol Title
B12 (On Hold) Phase II https://clinicaltrials.gov/ct2/show/NCT04553770	Neoadjuvant *HR+ HER2 Low expressing*	Trastuzumab Deruxtecan +/- Anastrozole	•Previously untreated operable invasive carcinoma of the breast > 2.0 cm, T2 with N0 or N1/N2. HR+ HER2 1+ or 2+ •No prior systemic therapy for invasive cancer. Prior tamoxifen therapy for DCIS is allowed but no prior aromatase inhibitor, no prior chemotherapy and no prior HER2-target therapy	A Phase II, Multicenter, Open-Label Trial to Evaluate the Safety and Efficacy of Trastuzumab Deruxtecan (DS-8201a) With or Without Anastrozole for HER2 Low Hormone Receptor Positive (HR+) Breast Cancer in the Neoadjuvant Setting
Roche/TRIO45/GO42784 Phase III https://clinicaltrials.gov/ct2/show/NCT04961996	Adjuvant *ER+HER2-*	Giredestrant Vs Endocrine Therapy of Physician's Choice	•Patient must have undergone definitive surgery and have received neoadjuvant chemotherapy. Patient who received or will be receiving adjuvant chemotherapy must have completed. A wash out period of 21 days is required. •If received (neo)adjuvant chemotherapy and/or had surgery within 12 months of surgery and had no prior endocrine therapy are eligible. •Patient is not receiving a CDK4/6 inhibitor as adjuvant therapy •No prior endocrine treatment. If patient is currently receiving adjuvant endocrine therapy, may receive up to 4 weeks until randomization.	A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Adjuvant Giredestrant Compared With Physician's Choice of Adjuvant Endocrine Monotherapy in Patients With Estrogen Receptor-Positive, HER2-Negative Early Breast Cancer
Celcuity CELC-G-301 (VIKTORIA-1) Phase III https://clinicaltrials.gov/ct2/show/NCT05501886	*HR+ HER2-* Advanced/Metastatic Second line	Gedatolisib with Fulvestrant +/- Palbociclib	•Confirmed diagnosis of ER+ and/or PR + and HER2- mBC •Progressed during or after CDK4/6 inhibitor combination in treatment with non-steroidal aromatase inhibitor •Subject will be assessed for PIK3CA status and then randomized to treatment arms according to PIK3CA mutation status. •No prior treatment with PI3K inhibitor, a protein kinase B (Akt) inhibitor or mTOR inhibitor •No prior treatment with a chemotherapy and antibody drug conjugates for advanced diseases. No more than 2 lines of prior endocrine therapy •Bone only disease that is only blastic with no soft tissue component is not permitted. •Subject with no h/o type 1 DM or uncontrolled type 2 diabetes	Phase 3, Open-Label, Randomized, Study Comparing Gedatolisib Combined With Fulvestrant & With or Without Palbociclib to Standard-of-Care Therapies in Patients With HR-Positive, HER2-Negative Advanced Breast Cancer Previously Treated With a CDK4/6 Inhibitor in Combination w/Non-Steroidal Aromatase Inhibitor Therapy

BREAST

TRIO				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Gilead GS-US 6238 ASCENT-03 Phase III https://clinicaltrials.gov/ct2/show/NCT05382299	*TNBC* Advanced/Metastatic First line	Sacituzumab Govitecan Vs Chemo (TPC)	•Previously untreated locally advanced, inoperable or metastatic TNBC, whose tumors are PD-L1 negative at screening or PD-L1 positive at screening if they have received and anti-PD-L1 inhibitor in the (neo)adjuvant setting. •Patient must have completed treatment for Stage I-III breast cancer and 6 months must have elapsed between completion of treatment and recurrence. Prior anti-PD-L1 use allowed in the curative setting •Patient present with de novo metastatic TNBC are eligible •PD-L1 and TNBC status centrally confirmed •Not have previously received topoisomerase 1 inhibitors	A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors Do Express PD-L1
Gilead GS-US 6173 ASCENT-04 Phase III https://clinicaltrials.gov/ct2/show/NCT05382286	*TNBC* Advanced/Metastatic First line	Pembro + SG Vs Pembro + Chemo (TPC)	•Locally advanced or metastatic TNBC who have not received previous systemic therapy and whose tumors are PD-L1 positive at screening. •Patient must have completed treatment for Stage I-III breast cancer and 6 months must have elapsed between completion of treatment and recurrence. Prior anti-PD-L1 use allowed in the curative setting. •Patient present with de novo metastatic TNBC are eligible •PD-L1 and TNBC status centrally confirmed •Not received prior therapy with agent directed to another stimulatory or coinhibitory T-cell receptor (e.g., CTLA-4, OX-40, CD137). •Not have previously received topoisomerase 1 inhibitors	A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1

BREAST

TEMPUS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
AstraZeneca Destiny Breast 11 Phase III https://clinicaltrials.gov/ct2/show/NCT05113251	HR-, HER2+ Neoadjuvant Locally advanced or inflammatory breast cancer	Trastuzumab Deruxtecan (T-DXd) or T-DXd f/b THP or ddAC-THP	•HER2 positive and ER/PR negative early breast cancer (EBC), Clinical Stage T0-4 (inclusive of inflammatory breast cancer), N1-3, M0 or ≥ T3, N0, M0 •No prior h/o invasive breast cancer •No h/o DCIS except for participants treated with mastectomy only > 5 years prior to current diagnosis. •No prior systemic therapy for the treatment of breast cancer. •No previous treatment with anthracyclines, cyclophosphamide, or taxanes for any malignancy.	A Phase 3 Open-label Trial of Neoadjuvant Trastuzumab Deruxtecan (T-DXd) Monotherapy or T-DXd Followed by THP Compared to ddAC-THP in Participants With High-risk HER2-positive Early-stage Breast Cancer (DESTINY-Breast11)
AstraZeneca (CAMBRIA-1) Phase III https://clinicaltrials.gov/ct2/show/NCT05774951	ER+/HER2- Early-stage resected Breast Cancer	Camizestrant Vs Standard ET	•Histologically confirmed ER+/HER2- early-stage resected invasive breast cancer with high or intermediate risk of recurrence •Completed adequate locoregional therapy (surgery with or without radiotherapy) for the primary breast tumor, with or without (neo)adjuvant chemotherapy •Completed at least 2 years but no more than 5 years (+3 months) of adjuvant ET •Prior adjuvant therapy with CDK4/6 inhibitors for 2 years is allowed •No previous treatment with camizestrant, investigational SERDs/investigational ER targeting agents, or fulvestrant	A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy With Camizestrant Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients With ER+/HER2- Early Breast Cancer
AstraZeneca TROPION-Breast-02 Phase III https://clinicaltrials.gov/ct2/show/NCT05374512	TNBC Recurrent or metastatic Who are not candidate for PD-L1 inhibitor First line	Dato-DXd Vs IV's choice of chemotherapy	•Histologically or cytologically documented locally recurrent inoperable or metastatic TNBC. •No prior chemotherapy or targeted systemic therapy for metastatic or locally recurrent inoperable breast cancer. •Not a candidate for PD-1/PD-L1 inhibitor therapy •Eligible for one of the chemotherapy options listed as ICC (paclitaxel, nab-paclitaxel, capecitabine, carboplatin, or eribulin), per investigator assessment.	A Phase 3, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) Versus Investigator's Choice of Chemotherapy in Patients Who Are Not Candidates for PD-1/PD-L1 Inhibitor Therapy in First-line Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION Breast02)

TEMPUS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
AstraZeneca Destiny Breast 09 Phase III https://clinicaltrials.gov/ct2/show/NCT04784715	HR+/-, HER2+ Advanced/Metastatic Treatment Naïve in the metastatic setting	Trastuzumab Deruxtecan (T-DXd) With or Without Pertuzumab vs Taxane, Trastuzumab and Pertuzumab	•Advanced or metastatic HR+/- , HER2+ breast cancer •No prior chemotherapy or HER2-targeted therapy for advanced or metastatic breast cancer or only 1 previous line of endocrine therapy in the metastatic setting. If received chemotherapy or HER2-targeted therapy in the neo-adjuvant or adjuvant setting are eligible if > 6 months from treatment to metastatic diagnosis. •No prior treatment with trastuzumab deruxtecan	Phase III Study of Trastuzumab Deruxtecan (T-DXd) With or Without Pertuzumab Versus Taxane, Trastuzumab and Pertuzumab in HER2-positive, First-line Metastatic Breast Cancer (DESTINY-Breast09)
AstraZeneca (SERENA-4) Phase III https://clinicaltrials.gov/ct2/show/NCT04711252	ER+, HER2- Advanced or Metastatic First line	AZD9833 (oral SERD) or anastrozole + Palbociclib	•ER+, HER2-breast cancer, De novo Stage 4 disease, or recurrence after standard adjuvant endocrine therapy meeting either one criteria: (1)Received at least 24 months of AI treatment as adjuvant therapy and at least 12 months have elapsed since the last dose of adjuvant AI therapy without disease progression on treatment (2)Received at least 24 months of tamoxifen as adjuvant endocrine therapy •Previously untreated with any systemic anti-cancer therapy for metastatic •No previous neoadjuvant or adjuvant treatment with an AI treatment +/-CDK4/6 inhibitor with disease recurrence while on or within 12 months of completing treatment	A Randomized, Double-Blind, Phase III Study of AZD9833 (an Oral SERD) Plus Palbociclib Versus Anastrozole Plus Palbociclib for the Treatment of Patients With Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer Who Have Not Received Any Systemic Treatment for Advanced Disease
Astrazeneca (SERENA-6) Phase III https://clinicaltrials.gov/ct2/show/NCT04964934	*ER+HER2-* Advanced/Metastatic with *ESR1 mutation* Subsequent line	AZD8933 or continuing AI + CDK4/6 inhibitor (Palbociclib or Abemaciclib)	•ER+, HER2- recurrent or metastatic adenocarcinoma of breast •ESR1m positive by central testing of ctDNA •Currently on AI + CDK4/6 +/- LHRH received ≥6 months as initial endocrine treatment for advance disease •No previous treatment with AZD9833, investigational SERDs or fulvestrant •Patient with controlled or asymptomatic CNS metastases	A Phase III, Double-blind, Randomized Study to Assess Switching to AZD9833 (a Next Generation, Oral SERD) + CDK4/6 Inhibitor (Palbociclib or Abemaciclib) vs Continuing Aromatase Inhibitor (Letrozole or Anastrozole)+ CDK4/6 Inhibitor in HR+/HER2-MBC Patients With Detectable ESR1Mutation Without Disease Progression During 1L Treatment With Aromatase Inhibitor+ CDK4/6 Inhibitor- A ctDNA Guided Early Switch Study

BREAST

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
BriaCell (BRI-ROL-001) Phase II https://clinicaltrials.gov/show/NCT03328026	*HER2+ and ER+, PR+;* *HER2+ and ER-, PR-;* *HER2- and ER+/PR+;* *TNBC* Advanced/Metastatic Subsequent line	SV-BR-1-GM + Retifanlimab	•Histologically confirmed breast cancer with recurrent and/or metastatic lesions and have failed prior therapy. • For patients with metastatic disease: ➢ HER2 positive and ER or PR positive tumors: must be refractory to hormonal therapy (e.g., aromatase inhibitor, tamoxifen or fluvestrant) and previously treated with at least 2 regimens including at least two anti-HER2 agents (e.g., trastuzumab and pertuzumab). ➢ HER2 positive and ER and PR negative tumors: must have failed at least 2 regimens including at least two anti-HER2 agents (e.g., trastuzumab and pertuzumab). ➢ HER2 negative and either ER or PR positive tumors: must be refractory to hormonal therapy and previously treated with at least 2 chemotherapy containing regimens. ➢ Triple Negative tumors: Must have exhausted other available therapies including prior treatment with a taxane and carboplatin. • Patient with treated and stable brain metastases • No concurrent or recent chemotherapy, immunotherapy (except the SV-BR-1-GM regimen	A Phase I/II Study of the SV-BR-1-GM Regimen in Metastatic or Locally Recurrent Breast Cancer Patients in Combination with Retifanlimab

BLADDER

TEMPUS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Gilead TROPHY U-01 Phase II https://clinicaltrials.gov/ct2/show/NCT03547973	Urothelial cancer Advanced/Metastatic Subsequent line	Sacituzumab Govitecan	• Patient with histologically confirmed Urothelial cancer Cohort 1: Progression or recurrence of urothelial cancer following receipt of platinum containing regimen and anti-PD-1 Cohort 2: Were ineligible for platinum-based therapy for 1st line metastatic disease and progression or recurrence after a first line therapy with anti-PD-1 Cohort 3: Progression or recurrence following a platinum containing regimen or within 12 months of completion of platinum-based therapy as neo(adjuvant) therapy Cohort 4: Individuals has not received any platinum-based chemotherapy in the metastatic setting. Cohort 5: Individuals received at least 4 cycles and no more than 6 cycles of GEM + Cisplatin Cohort 6: Cis-ineligible and no prior therapy for metastatic disease.	A Phase II Open-Label Study of Sacituzumab Govitecan in Unresectable Locally Advanced/Metastatic Urothelial Cancer

CNS

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Fore Biotherapeutics (F8294-201b) Phase II https://clinicaltrials.gov/ct2/show/NCT05503797	*BRAFV600E alteration* Primary CNS tumors, Solid Tumors (No standard/acceptable treatment)	FORE8394	• Group A: ➢ Patients with unresectable, locally advanced or metastatic solid tumors or primary CNS tumors harboring BRAF fusions. ➢ Received at least available standard therapy, and intolerant to available therapies, or not appropriate with standard therapy. ➢ No prior treatment with RAF/BRAF inhibitors for advanced unresectable or metastatic disease (such as tovorafenib) and MEK inhibitor • Group B: ➢ Participants with recurrent primary CNS tumors harboring BRAF V600E mutations. ➢ Have received at least one line of prior therapy including radiation. ➢ No prior treatment with BRAF, ERK, and/or MEK inhibitor • Patients with no known or suspected neurofibromatosis-1 (NF-1) and/or Ras related gene alterations.	A Phase 2 Master Protocol to assess the efficacy and safety of FORE8394, an inhibitor of BRAF class 1 and class 2 alterations, in participants with cancer harboring BRAF alterations

GASTROINTESTINAL

Research Study	Indication & Line of Therapy	Intervention	Key Criteria	Protocol Title
TRIO				
Amgen 20210098 Phase Ib/III https://clinicaltrials.gov/ct2/show/NCT05111626	Gastric or GEJ adenocarcinoma *FGFR2b overexpression* Advanced/Metastatic First line	mFOLFOX6 & Nivolumab +/- Bemarituzumab	•No prior treatment for metastatic or unresectable disease except for a maximum of 1 dose of mFOLFOX6 with or without nivolumab. •Prior adjuvant, neo-adjuvant, and peri-operative therapy is allowed, it has been completed > 6 months •No prior treatment with FGF inhibitor •No Known positive human epidermal growth factor receptor 2 (HER2) status •Patient with treated and asymptomatic CNS metastases	A Phase 1b/3 Study of Bemarituzumab Plus Chemotherapy and Nivolumab Versus Chemotherapy and Nivolumab Alone in Subjects With Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer With FGFR2b Overexpression
TEMPUS				
Inspirna RGX-202-01 Phase I https://clinicaltrials.gov/ct2/show/NCT03597581	*RAS mutant* CRC Advanced/Metastatic (Previously treated with FOLFIRI or other irinotecan containing regimens)	RGX-202-101	•Patient must have a RAS mutant locally advanced or metastatic colorectal cancer of adenocarcinoma or poorly differentiated histology and must have disease that is resistant to or relapsed following available SOC or for which there is no standard systemic therapy or reasonable therapy •For RGX-202-01 plus FOLFIRI and bevacizumab expansion stages: ▫ Must have received only one prior standard of care oxaliplatin-containing regimen ▫ Must have received prior treatment with pembrolizumab if the patient has dMMR/MSI-H colorectal cancer ▫ May have received prior treatment with bevacizumab, cetuximab, or panitumumab, or an FDA approved biosimilar.	A Phase 1 Study of RGX-202-01, a Small Molecule Inhibitor of the Creatine Transporter SLC6a8, as a Single Agent and as Combination Therapy in Patients With Advanced Gastrointestinal Malignancies With Select Expansion Cohorts

GASTROINTESTINAL

Research Study	Indication & Line of Therapy	Intervention	Key Criteria	Protocol Title
Tempus/CARIS				
Mirati KRYSTAL-10 Phase III https://clinicaltrials.gov/ct2/show/NCT04793958	*KRAS G12C* CRC Advanced/Metastatic Second line	MRTX849 (Adagrasib) + Cetuximab or FOLFIRIOX	•Prior therapy in 1st line with Oxaliplatin or irinotecan. •No prior treatment with KRAS G12C or anti-EGFR antibody (cetuximab or panitumumab)	A Randomized Phase 3 Study of MRTX849 in Combination With Cetuximab Versus Chemotherapy in Patients With Advanced Colorectal Cancer With KRAS G12C Mutation With Disease Progression On or After Standard First-Line Therapy
CARIS				
Redx Pharma Plc (RXC004/0002) Phase II https://clinicaltrials.gov/show/NCT04907539	*RNF43 or RSPO2, RSPO3* Metastatic MSS CRC Subsequent line	RXC004	• Metastatic Colorectal cancer (CRC), and (1) documented tumor tissue aberration in RNF43 and/or RSPO, (2) confirmation of microsatellite stable (MSS) status • Patients must have had documented radiological progression following a minimum of 1 prior SOC treatment regimen for metastatic disease • Patient with no known or suspected brain metastases	A Multi-arm, Phase II, Open-Label, Multicentre Study to Assess the Preliminary Efficacy of RXC004 in Monotherapy and in Combination with Nivolumab, in Patients with Ring Finger Protein 43 (RNF43) or R-spondin (RSPO) Aberrated, Metastatic, Microsatellite Stable, Colorectal Cancer who have Progressed following Therapy with Current Standard of Care

Tempus				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Bristol-Myers Squibb CA116001 Phase II https://clinicaltrials.gov/ct2/show/NCT05613088	High grade serous (HGS) ovarian, primary peritoneal or fallopian tube cancer Platinum-resistant disease	MORAb-202 (Farletuzumab Ecteribulin Vs Investigator's choice of chemotherapy {Paclitaxel, Pegylated Liposomal Doxorubicin (PLD),Topotecan}	•Histologically-confirmed HGS ovarian, primary peritoneal, or fallopian tube cancer. •Platinum-resistant disease, defined as: ▫ For participants who had only 1 line of platinum-based therapy: progression between > 1 month and ≤ 6 months after the last dose of platinum-based therapy of at least 4 cycles. ▫ For participants who had 2 or 3 lines of platinum-based therapy: progression ≤ 6 months after the last dose of platinum-based therapy. ▫ Participants have received at least 1 but no more than 3 prior lines of systemic therapy and for whom single-agent therapy is appropriate as the next line of therapy. Participants may have been treated with up to 1 line of therapy subsequent to determination of platinum-resistance. •No Clear cell, mucinous, endometrioid or sarcomatous histology, or mixed tumors, or low grade or borderline ovarian cancer.	A Phase 2 Open-label Randomized Study of Farletuzumab Ecteribulin (MORAb-202), a Folate Receptor Alpha-targeting Antibody-drug Conjugate, Versus Investigator's Choice Chemotherapy in Women With Platinum-resistant High-grade Serous (HGS) Ovarian, Primary Peritoneal, or Fallopian Tube Cancer

HEMATOLOGIC MALIGNANCY

TEMPUS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
AbbVie ReVenG (M20-356) Phase II https://clinicaltrials.gov/ct2/show/NCT04895436	CLL Response on partial remission on Venetoclax + Obinutuzumab (VenG) as first-line therapy	Obinutuzumab + Venetoclax	•Documented diagnosis of chronic lymphocytic leukemia (CLL) •Previously completed venetoclax + obinutuzumab (VenG) regimen as a fixed duration first-line (1L) therapy and achieved complete remission, complete remission with incomplete marrow recovery, partial remission, or nodular partial remission. •More than 24 months (Cohort 1) or 12-24 months (Cohort 2) have elapsed between last dose of venetoclax and disease progression after completion of 1L VenG treatment. •Not Received intervening treatment for CLL after previous treatment with VenG.	A Multicenter, Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of Venetoclax-Obinutuzumab Retreatment in Patients With Recurring Chronic Lymphocytic Leukemia

Liposarcoma

OPN/TEMPUS/CARIS				
Boehringer Ingelheim (Brightline-1) Phase II/III https://clinicaltrials.gov/ct2/show/NCT05218499	MDM2-amplified Dedifferentiated Liposarcoma (DDLPS) First Line	BI 907828	•Locally advanced or metastatic, progressive or recurrent dedifferentiated liposarcoma (DDLPS) with positive mouse double minute 2 homolog (MDM2) immunohistochemistry or MDM2 amplification •No Known mutation in the TP53 gene (screening for TP53 status is not required). •No prior systemic therapy for liposarcoma in any setting (including adjuvant, neoadjuvant, maintenance, palliative) •No previous treatment with anthracyclines in any setting (systemic treatment with other anticancer agent is allowed if completed at least 5 years)	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

CANCER & BLOOD SPECIALITY CLINIC

OPN

Research Study	Indication & Line of Therapy	Intervention	Key Criteria	Protocol Title
Shanghi Henilus Biotech (CBSC) Phase III https://clinicaltrials.gov/ct2/show/NCT05468489	ES-SCLC Tx. Naive	HLX10 or Atezolizumab + Carboplatin/Etoposide	•No prior systemic therapy for ES-SCLC. •Patients who received chemoradiotherapy for previous limited stage SCLC must be treated and have a treatment-free interval of at least 6 months •Patient with stable brain metastases	A Randomized, Open-label Study of HLX10 Plus Chemotherapy (Carboplatin-Etoposide) in Comparison With Atezolizumab Plus Chemotherapy in Previously Untreated US Patients With Extensive Stage Small Cell Lung Cancer (ES-SCLC)
Teligene SZCT-2020-06 Phase IIb https://clinicaltrials.gov/ct2/show/NCT05168566	NSCLC EGFR L861Q, G719X, S768I Advanced/Metastatic TKI Naive	Sutetinib Maleate	•Advanced or metastatic NSCLC which harbors uncommon EGFR mutation (L861Q, G719X and S768I) with ≤ 1 prior line of chemotherapy. •No prior Tx with EGFR TKI •No systemic anti-tumor therapy such as chemotherapy, immunotherapy and radiation therapy used within 4 weeks prior to enrollment. •Patient with stable brain metastases	A Multicenter, Open-label, Phase IIb Study to Evaluate the Efficacy and Safety of Sutetinib Maleate Capsule in Locally Advanced or Metastatic NSCLC (Non-resistant Uncommon EGFR Mutations Only, Including L861Q, G719X, and/or S768I)
Revolution Medicines, Inc RMC-4630-03 Phase II https://clinicaltrials.gov/ct2/show/NCT05054725	NSCLC *KRAS G12C +* Advanced/Metastatic Subsequent line	RMC-4630 + Sotorasib	•Has progressed on prior standard therapies (no more than 3 prior lines of therapies) •No prior therapy with KRASG12C inhibitor and/or SHP2 inhibitor •No primary CNS tumor • Patient with treated and stable brain metastases	A Phase 2, Open-Label, Multicenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer Subjects With KRASG12C Mutation After Failure of Prior Standard Therapies
Effector Therapeutics Eft508 (USC) Phase II https://clinicaltrials.gov/ct2/show/NCT04622007	NSCLC *PD-L1+* Advanced/Metastatic First Line	Tomivosertib (eFT508) or Placebo + Pembrolizumab	Cohort B (open for enrollment) • Are eligible for single-agent pembrolizumab for advanced/metastatic NSCL and have tumor PD-L1 ≥50% •Must not have been treated previously with platinum-based chemotherapy in the advanced/metastatic setting. If received in the neo/adjuvant setting, therapy was >9 months prior to randomization •No NSCLC with EGFR or ALK genomic tumor aberrations •Patient with treated and asymptomatic brain metastases Cohort A and Cohort C (closed for accrual)	A Randomized, Double-Blind, Placebo-Controlled Trial of Tomivosertib in Combination With Anti-PD-(L)1 Therapy in Subjects With NSCLC as First Line Therapy or When Progressing on Single-Agent First-Line Anti PD (L)1 Therapy

LUNG

SITE STUDIES (NON-TRIO)				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
AbbVie (M22-137) Phase II https://clinicaltrials.gov/ct2/show/NCT05513703	MET amplified NSCLC (Non-Squamous) Advanced/Metastatic First line	Telisotuzumab vedotin	•Locally advanced or metastatic non-squamous cell NSCLC and must have MET amplification •No alterations in EGFR, ALK, ROS1 or BRAF that predict sensitivity to targeted therapy •No prior systemic therapy for locally advanced/metastatic NSCLC Not received prior c-Met-targeted antibodies •Patients with treated and stable CNS metastases	Phase 2, Open-Label Study in Subjects With Previously Untreated MET Amplified Locally Advanced/Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC)
Lantern Pharma (HARMONIC) Phase II https://clinicaltrials.gov/ct2/show/NCT05456256	Relapsed NSCLC- Adenocarcinoma Advanced/Metastatic Second line	Pemetrexed and Carboplatin +/- LP-300	•Locally advanced or metastatic primary adenocarcinoma of lung (including bronchioalveolar cell carcinoma) with specific actionable genomic alterations (e.g., ROS1, MET, BRAF, ALK, EGFR, NTRK fusion, etc.). •Patients must be never smokers: who has never smoked, or who has smoked less than 100 cigarettes in his or her lifetime. •Patients who have received with TKIs for NSCLC but have experienced disease progression, unacceptable TKI-related toxicities, or are unable to tolerate the further use of TKIs. •Patients who have not received prior systemic chemotherapies or hormonal therapies for NSCLC(excluding dexamethasone or corticosteroids) or have not received any prior immunotherapies. •Patient with treated and stable CNS metastases.	Phase II Trial of LP-300 in combination with carboplatin and pemetrexed in never smoker Patients with relapsed advanced primary adenocarcinoma of the lung after treatment with Tyrosine Kinase Inhibitors
TRIO				
Effector Therapeutics Eft508 (USC) Phase II https://clinicaltrials.gov/ct2/show/NCT04622007	NSCLC *PD-L1+* Advanced/Metastatic First Line	Tomivosertib (eFT508) or Placebo + Pembrolizumab	Cohort B (open for enrollment) • Are eligible for single-agent pembrolizumab for advanced/metastatic NSCL and have tumor PD-L1 ≥50% •Must not have been treated previously with platinum-based chemotherapy in the advanced/metastatic setting. If received in the neo/adjuvant setting, therapy was >9 months prior to randomization •No NSCLC with EGFR or ALK genomic tumor aberrations •Patient with treated and asymptomatic brain metastases Cohort A and Cohort C (closed for accrual)	A Randomized, Double-Blind, Placebo-Controlled Trial of Tomivosertib in Combination With Anti-PD-(L)1 Therapy in Subjects With NSCLC as First Line Therapy or When Progressing on Single-Agent First-Line Anti PD (L)1 Therapy

LUNG

TEMPUS				
AstraZeneca PACIFIC-4 Phase II https://clinicaltrials.gov/ct2/show/NCT03833154	NSCLC unresected Stage I/II T1 to T3N0M0	Durvalumab, SBRT	Main Cohort •Planned SoC SBRT as definitive treatment for patient with unresected Stage I/II lymph node-negative (T1 to T3N0M0) NSCLC •EGFR testing is strongly recommended prior to enrollment. Patient with tumor harboring EGFR will be removed from main cohort Osimertinib Cohort •Confirmation that the tumor harbors one of the 2 common EGFR mutations (Ex19del, L858R) •Patient will receive Osimertinib after completion of SoC SBRT •Not received treatment with any of the following ▫ Preoperative or adjuvant platinum-based or other chemotherapy for the disease under investigation ▫ Prior treatment with neoadjuvant or adjuvant EGFR TKI	A Phase III, Randomized,(1:1), Placebo-controlled, Double-blind, Multi-center, International Study of Durvalumab With Stereotactic Body Radiation Therapy (SBRT) for the Treatment of Patients With Unresected Stage I/II, Lymph-node Negative Non-small Cell Lung Cancer (PACIFIC-4/RTOG-3515) Osimertinib Following SBRT, a Single Arm Cohort for Patients With Unresected Stage I/II, Lymph Node Negative NSCLC Harboring a Sensitizing EGFR Mutation
Revolution Medicines, Inc RMC-4630-03 Phase II https://clinicaltrials.gov/ct2/show/NCT05054725	*KRAS G12C* NSCLC Advanced/Metastatic Second /Subsequent line	RMC-4630 + Sotorasib	•Has progressed on prior standard therapies (no more than 3 prior lines of therapies) •No prior therapy with KRASG12C inhibitor and/or SHP2 inhibitor •No primary CNS tumor •Brain metastases is eligible if the patient was previously treated and stable	A Phase 2, Open-Label, Multicenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer Subjects With KRASG12C Mutation After Failure of Prior Standard Therapies
Turning point TPX-0005-01 Phase II https://clinicaltrials.gov/ct2/show/NCT03093116	*ROS1 fusion* Advanced/Metastatic Subsequent line	Repotrectinib	•Locally advanced or metastatic solid tumor (including primary CNS tumors) that harbors an ROS1, NTRK1, NTRK2, or NTRK3 gene rearrangement •TKI naïve or prior TKI (no more than 2 prior TKIs). No more than 1 prior chemotherapy •Patients with asymptomatic CNS metastases	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)

TEMPUS				
Janssen Paloma-2 Phase II https://clinicaltrials.gov/ct2/show/NCT05498428	*EGRF, Exon19del* or *Exondel21, L858R NSCLC* Advanced/Metastatic	Amivantamab SC-CF	•Additional Cohort specific disease requirements include; Cohorts 1: EGFR exon 19/L858R NSCLC, previously untreated (First line) Cohort 2: EGFR Exon 20 NSCLC, previously untreated (First line) Cohort 3: Exon19/L858R NSCLC, post Osimertinib (Second line) Cohort 4: Previously Treated with Amivantamab IV, switch from Amivantamab IV to SC •Participant is currently receiving medications or herbal supplements known to be potent Cytochrome (CYP3A4/5) inducers and is unable to stop use for an appropriate washout period prior to Cycle 1 Day 1	A Phase 2, Open-Label, Parallel Cohort Study of Subcutaneous Amivantamab in Multiple Regimens in Patients With Advanced or Metastatic Solid Tumors Including EGFR-mutated Non-Small Cell Lung Cance
Janssen Paloma-3 Phase III https://clinicaltrials.gov/ct2/show/NCT05388669	*EGRF, Exon19del* or *Exondel21, L858R NSCLC* Advanced/Metastatic Subsequent line	Lazertinib Amivantamab	•Histologically or cytologically confirmed, locally advanced or metastatic, NSCLC, either EGFR Exon 19del or Exon 21 L858R mutation •Prior Treatment: must have progressed on or after Osimertinib (or another approved 3rd generation EGFR TKI) and platinum-based chemotherapy (irrespective of order). •Patient with treated and asymptomatic brain metastases	A Phase 3, Open-label, Randomized Study of Lazertinib With Subcutaneous Amivantamab Compared With Intravenous Amivantamab in Patients With EGFR-mutated Advanced or Metastatic Non-small Cell Lung Cancer After Progression on Osimertinib and Chemotherapy
Janssen Mariposa-2 Phase III https://clinicaltrials.gov/ct2/show/NCT04988295	*EGFR Exon19del or Exon 21 L858R Non-squamous NSCLC* Advanced/Metastatic After Osimertinib failure	Platinum based chemotherapy +/- Amivantamab and Lazertinib	•Histologically or cytologically confirmed, locally advanced or metastatic, non-squamous NSCLC, either EGFR Exon 19del or Exon 21 L858R mutation •Participant must have progressed on or after Osimertinib monotherapy as the most recent line of treatment. •Osimertinib must have been administered as either the first-line or in the second- line setting after prior treatment with first- or second-generation EGFR TKI as a monotherapy	A Phase 3, Open-Label, Randomized Study of Amivantamab and Lazertinib in Combination With Platinum-Based Chemotherapy Compared With Platinum-Based Chemotherapy in Patients With EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer After Osimertinib Failure
ArriVent FURMO-004 Phase III https://clinicaltrials.gov/ct2/show/NCT05607550	*EGFR Exon 20 Non-squamous NSCLC* Advanced/Metastatic First line	Fumoenertinib	•Locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutation •No prior systemic anticancer therapy regimens received for locally advanced or metastatic NSCLC including prior treatment with any *EGFR*-targeting agents (e.g., previous *EGFR* TKIs, monoclonal antibodies, or bispecific antibodies) •Patients who have received prior neo-adjuvant and/or adjuvant chemotherapy, immunotherapy, or chemoradiotherapy for non-metastatic disease must have experienced a treatment free interval of at least 12 months.	A Global, Phase 3, Randomized, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of Furmonertinib Compared to Platinum-Based Chemotherapy as First-Line Treatment for Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With Epidermal Growth Factor Receptor Exon 20 Insertion Mutations

LUNG

TEMPUS				
AstraZeneca Destiny Lung 04 Phase III https://clinicaltrials.gov/ct2/show/NCT05048797	HER2 Exon 19 or 20 mutations NSCLC Advanced/Metastatic Treatment naive	Trastuzumab Deruxtecan (T-DXd)	•Locally advanced or metastatic non-squamous NSCLC with HER2 mutation in exons 19 or 20 •Treatment-naïve for palliative intent systemic therapy for locally advanced or metastatic disease •Tumors with no targetable alterations to EGFR (or other targetable mutations including but not limited to ALK •Patient with treated brain metastases	An Open-label, Randomized, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Trastuzumab Deruxtecan as First-line Treatment of Unresectable, Locally Advanced, or Metastatic NSCLC Harboring HER2 Exon 19 or 20 Mutations (DESTINY-Lung04)
Dizal WU-KONG1 Phase II https://clinicaltrials.gov/ct2/show/NCT03974022	EGFR/ HER2 Exon20 ins mutations NSCLC Advanced/Metastatic	DZD9008	•Locally advanced or metastatic NSCLC with EGFR/HER2 exon20 ins mutations •Patients should have received at least 1 line but no more than 3 lines of systemic therapy except Dose expansion Cohort 5 who have not received prior systemic therapy (treatment naïve) •Patients who have not received prior treatment with poziotinib or TAK788 or other EGFR/HER2 exon20 insertion inhibitors •Not treated with EGFR or HER2 antibodies, major surgery or onco-immunotherapy (e.g., Immune check point inhibitor PD-L1, CTLA-4) within 4 weeks before screening	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
TEMPUS/CARIS				
Mirati KRYSTAL-7 Phase II https://clinicaltrials.gov/ct2/show/NCT04613596	*KRAS G12C* NSCLC Metastatic (squamous/non-squamous) First line	MRTX849 + Pembrolizumab	•Metastatic NSCLC (squamous or non-squamous) with KRAS G12C mutation and known PD-L1 status •No prior systemic treatment for advanced/metastatic NSCLC •No active brain metastases	A Phase 2 Trial of MRTX849 Monotherapy and in Combination With Pembrolizumab in Patients With Advanced Non-Small Cell Lung Cancer With KRAS G12C Mutation

PROSTATE

Research Study	Indication & Line of Therapy	Intervention	Key Criteria	Protocol Title
TRIO				
Lilly I3Y-MC-JPEG Phase III https://clinicaltrials.gov/ct2/show/NCT05288166	High-Risk mHSPC First -Line	Abemaciclib/Placebo + Abiraterone and Prednisone (Stratification factors: De novo mHSPC, visceral metastases, prior docetaxel)	•Histologically confirmed adenocarcinoma of the prostate •High-risk metastatic disease prior to the initiation of systemic therapy (ADT ± docetaxel) mHSPC defined as: ≥4 bone metastases by bone scan AND/OR ≥1 visceral metastases by CT/MRI •Participants must have initiated ADT prior to randomization. •Not received any prior systemic therapy for metastatic prostate cancer, the following exceptions are permitted; up to 3 months of ADT (without docetaxel) OR up to 6 cycles of docetaxel with ADT, AND absence of radiographic or PSA progression. ·No prior treatment with abemaciclib or any other CDK4 & 6 inhibitor ·Patient with treated CNS metastases	CYCLONE 3: A Phase 3, Randomized (1:1), Double-Blind, Placebo-Controlled Study of Abemaciclib in combination with Abiraterone plus prednisone in men with High-Risk Metastatic Hormone-Sensitive Prostate Cancer
TEMPUS				
Janssen PCR3002 (AMPLITUDE) Phase III https://clinicaltrials.gov/ct2/show/NCT04497844	*BRCA1, BRCA2, BRIP1, CHEK2,FANCA, PALB2, RAD51B, RAD54L mutation* mCSPC Subsequent line	Niraparib (JNJ-64091742) or Placebo + Abiraterone Acetate	•Metastatic prostate adenocarcinoma, mCSPC; must have HRR gene alteration •Androgen deprivation therapy (either medical or surgical castration) must have been started >=14 days •Other allowed prior therapy for mCSPC (a) maximum of 1 course of radiation and 1 surgical intervention (b) <6 months of ADT therapy (c) no more than 45 days of AA-P (d) up to a maximum of 2 weeks of ketoconazole for prostate cancer •No prior treatment wit PARP-inhibitor •History or current diagnosis of myelodysplastic syndrome/AML	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants With Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)
AstraZeneca CAPItello-281 Phase III https://clinicaltrials.gov/ct2/show/NCT04493853	*PTEN* Deficiency Denovo meatastatic HSPC First line	Capivasertib + Abiraterone	•Asymptomatic or mildly symptomatic, histologically-confirmed de novo hormone-sensitive prostate adenocarcinoma with PETN deficiency •No prior chemotherapy allowed •Candidate for abiraterone and steroid therapy •Ongoing ADT with GnRH analogue, or LHRH agonists or antagonist, or bilateral orchiectomy is from 0 days to a max. of 93 days prior to randomization	A Phase III Double-Blind, Randomised, Placebo-Controlled Study Assessing the Efficacy and Safety of Capivasertib+Abiraterone Versus Placebo+Abiraterone as Treatment for Patients With DeNovo Metastatic Hormone-Sensitive Prostate Cancer Characterised by PTEN Deficiency

SOLID TUMOR

TEMPUS				
Turning point TPX-0005-01 Phase II https://clinicaltrials.gov/ct2/show/NCT03093116	*NTRK 1-3 or ROS1 Fusion* Solid tumors Advanced/Metastatic Subsequent line	Repotrectinib	•Locally advanced or metastatic solid tumor (including primary CNS tumors)that harbors an ALK, ROS1, NTRK1, NTRK2, or NTRK3 gene rearrangement •TKI naïve or prior TKI (no more than 2 prior TKIs). No more than 1 prior chemotherapy •Patients with asymptomatic CNS metastases	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)
Tempus PAVO Phase II https://clinicaltrials.gov/ct2/show/NCT05169437	*PALB2 mutations* Solid tumors Advanced/Metastatic Subsequent line	Niraparib	•Locally advanced or metastatic solid tumor with PALB2 gene mutation and must have received all appropriate standard therapies •Patients with stable and asymptomatic CNS metastases •Not relapsed while receiving platinum-based therapy in the adjuvant/curative setting. •Not progressing within 14-18 weeks while receiving platinum-based therapy in the metastatic setting. •No PARP inhibitor in prior lines of treatment •No germline or somatic BRCA1 or BRCA2 mutations	A Single-Arm Phase-II Study of Niraparib in Locally Advanced or Metastatic Solid Tumor Patients With PALB2 Mutations
VM Oncology Phase I https://clinicaltrials.gov/ct2/show/NCT03556228	*NTRK1* alteration Any solid tumors or Lymphoma (No standard/acceptable treatment	VMD-928	•Positive result on TrkA immunohistochemistry •Diagnosis of any type of solid tumor or lymphoma that is not responsive to standard therapies	An Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of VMD-928 in Subjects With Solid Tumors or Lymphoma
Genmab GEN1042 Phase I/II https://clinicaltrials.gov/ct2/show/NCT04083599	Solid tumors Advanced/Metastatic (No standard/acceptable treatment)	GEN1042	Key Inclusion Criteria: Monotherapy-Dose escalation and Dose expansion •Non-CNS solid tumors whom there is no available standard therapy •Confirmed diagnosis of relapsed/refractory NSCLC, or CRC with no available standard therapy Combination therapy-Dose Expansion •Stage III or IV melanoma with no prior systemic anticancer therapy •Recurrent/Metastatic NSCLC with no prior systemic anticancer therapy, no actionable mutation •Recurrent/Metastatic HNSCC and tumor demonstrating PD-L1 •Metastatic pancreatic ducal adenocarcinoma with no previous radiotherapy, surgery, chemotherapy	A First-in-Human, Open-label, Dose-escalation Trial With Expansion Cohorts to Evaluate Safety and Anti-tumor Activity of GEN1042 in Subjects With Malignant Solid Tumors

SOLID TUMOR

TEMPUS				
Boehringer Ingelheim (Brightline-2) Phase II https://clinicaltrials.gov/ct2/show/NCT05512377	*MDM2* Biliary Tract Cancer, Pancreas Tumors and Solid Tumors Advanced/Metastatic (No standard/acceptable treatment)	BI 907828	•Diagnosis of a solid tumor which meets the criteria for: Cohort 1: Locally advanced or metastatic biliary tract adenocarcinoma (intra- and extrahepatic cholangiocarcinoma, gallbladder cancer, and ampullary cancer) Cohort 2: Locally advanced or metastatic pancreatic ductal adenocarcinoma Cohort 3: Locally advanced or metastatic lung adenocarcinoma Cohort 4: Locally advanced or metastatic urothelial bladder cancer •Patients must have unresectable disease and have received all appropriate standard therapies known to confer clinical benefit •No previous administration of BI 907828 or any other MDM2-p53 or mouse double minute 4 (MDMX, MDM4)-p53 antagonist.	Brightline-2: A Phase IIa/IIb, Open-label, Single-arm, Multi-center 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 Tumors
Fore Biotherapeutics (F8294-201b) Phase II https://clinicaltrials.gov/ct2/show/NCT05503797	*BRAFV600E alteration* Primary CNS tumors, Solid Tumors (No standard/acceptable treatment)	FORE8394	• Group A: ➢ Patients with unresectable, locally advanced or metastatic solid tumors or primary CNS tumors harboring BRAF fusions. ➢ Received at least available standard therapy, and intolerant to available therapies, or not appropriate with standard therapy. ➢ No prior treatment with RAF/BRAF inhibitors for advanced unresectable or metastatic disease (such as tovorafenib) and MEK inhibitor • Group B: ➢ Participants with recurrent primary CNS tumors harboring BRAF V600E mutations. ➢ Have received at least one line of prior therapy including radiation. ➢ No prior treatment with BRAF, ERK, and/or MEK inhibitor • Patients with no known or suspected neurofibromatosis-1 (NF-1) and/or Ras related gene alterations.	A Phase 2 Master Protocol to assess the efficacy and safety of FORE8394, an inhibitor of BRAF class 1 and class 2 alterations, in participants with cancer harboring BRAF alterations

SOLID TUMOR

TEMPUS/CARIS				
Mirati KRYSTAL-1 Phase II https://clinicaltrials.gov/ct2/show/NCT03785249	*KRAS G12C* Solid tumors Metastatic Subsequent line, first line for NSCLC Cohort E	MRTX849 (Adagrasib) {Cohort A, B, E, F} MRTX849 (Adagrasib) + Cetuximab {Cohort G)	•Metastatic solid tumor with KRAS G12C mutation a. Cohorts A, B, and E squamous or non-squamous NSCLC b. Cohorts C, F, and G, adenocarcinoma of the colon or rectum •Standard treatment is not available or patient declines; first-line treatment for NSCLC for certain cohorts •KRAS G12C mutation – All cohorts. STK11 mutation for Cohort E only. Prior treatment varies per cohort NSCLC-Cohort A and B: patients must have previously received at least a platinum-containing chemotherapy and checkpoint inhibitor therapy. NSCLC- Cohort E: patient must be in the first-line treatment setting. CRC-Cohort F: patient must have previously received standard treatment for metastatic disease, and must have at least a fluropyrimidine, irinotecan, oxaliplatin, and VEGF inhibitor (bevacizumab, ramucirumab, ziv-aflibercept) CRC in combination with cetuximab- Cohort G: patient must have previously received with fluropyrimidine, irinotecan, oxaliplatin, and a VEGF inhibitor.	A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients With Advanced Solid Tumors With KRAS G12C Mutation KRYSTAL-1

SOLID TUMOR

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Boehringer Ingelheim 1479-0001 Phase II https://clinicaltrials.gov/ct2/show/NCT04886804	HER2 TKD Solid tumors Advanced/Metastatic	BI 1810631	•Histologically or cytologically confirmed diagnosis of an advanced, unresectable and/or metastatic non-hematologic malignancy with HER2 aberrations Phase 1a -Patient who has failed conventional treatment or for whom no therapy of proven efficacy exists or who is not eligible for established treatment options. Phase 1b Cohort 1 -Patient who had received, in the advanced/metastatic setting, at least one line of systemic therapy Phase 1b Cohort 2 Treatment naïve for NSCLC.	An Open Label, Phase I Dose Escalation Trial, With Dose Confirmation and Expansion, of BI 1810631 as Monotherapy in Patients With Advanced or Metastatic Solid Tumors With HER2 Aberrations
Boehringer Ingelheim 1403-0001 Phase Ia/Ib https://clinicaltrials.gov/ct2/show/NCT03449381	TP53wt and MDM2 Solid tumors	BI 907828	•Pathologically documented, advanced solid tumors. Patients fulfilling one or more of the following criteria: -Radiologically documented disease progression or relapse -Patients who are not eligible to receive SOC treatments, and for whom no proven treatments exist. -Patients with MDM2 amplified sarcomas who require first line treatment (for Ph Ib/dose expansion - Cohort 1 only). Patients with MDM2 amplified sarcomas may fulfil any one of the above three criteria to be considered eligible. Phase Ia (Dose escalation) only: -Patient has a tumor with either a known TP53 wild type status, or unknown TP53 status, and regardless of MDM2 amplification status Phase Ib (Expansion phase) only: -***Cohort 1*****:** TP53 wt and MDM2-amplified sarcoma with advanced/metastatic disease at any line of therapy. -***Cohort 2***: TP53 wt and MDM2- amplified NSCLC, urothelial, gastric, biliary tract (including cholangiocarcinoma, intra- and extrahepatic biliary tree, gall blander and ampulla of vater) or pancreatic solid PDAC tumors who have had at least one previous line of therapy for advanced/metastatic disease.	A Phase Ia/Ib, Open Label, Multicenter, Dose-escalation Study of BI 907828 in Patients With Advanced or Metastatic Solid Tumors

SOLID TUMOR

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Boehringer Ingelheim 1403-0002 Phase Ia/Ib https://clinicaltrials.gov/ct2/show/NCT03964233	TP53wt Solid tumors Advanced/Metastatic	BI 907828 BI754091 BI 754111	•Patients with radiologically documented disease progression or relapse during or after all SOC treatments. •Previous treatment with an anti-PD-1/PD-L1 mAb is allowed as long as the last administration of the anti-PD-1/PD-L1 mAb on the previous treatment occurred a minimum of 28 days prior to the first administration of study treatment. •Phase Ia (dose escalation part): -Confirmed diagnosis of unresectable, advanced and/or metastatic solid tumors irrespective of the TP53 mutation status. •Phase Ia (Expansion Cohort): -Patients with MDM2 amplified tumors and TP53 wild type status confirmed on tumor tissue •Phase Ib (dose expansion part): -Patients with TP53 wild-type status confirmed on tumor tissue. ***Cohort 1***: Patients with unresectable, advanced and/or metastatic TP53 wt one line of systemic medical treatment: Liposarcoma excluding dedifferentiated liposarcoma, Undifferentiated pleomorphic sarcoma, Myxofibrosarcoma, Synovial sarcoma, Leiomyosarcoma ***Cohort 2:*** Patients with unresectable, advanced and/or metastatic TP53 wt MDM2-amplified tumors as listed below, who received at least one line of systemic medical treatment: NSCLC (patients with NSCLC harboring genomic aberrations for which approved targeted therapy is approved and available, must have received such prior treatment), Gastric adenocarcinoma, Urothelial carcinoma, Biliary tract carcinoma (including cholangiocarcinoma, intra-and extrahepatic biliary tree, gall bladder and ampulla of vater) •No previous administration of BI 907828 or any other MDM2-p53 or MDMX (MDM4)-p53 antagonist	A Phase Ia/Ib, Open Label, Dose-escalation Study of the Combination of BI 907828 With BI 754091 (Ezabenlimab) and BI 754111 and the Combination of BI 907828 With BI 754091(Ezabenlimab) Followed by Expansion Cohorts, in Patients With Advanced Solid Tumors

SOLID TUMOR

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Merus N.V. MCLA-128-CL01 Phase II https://clinicaltrials.gov/show/NCT02912949	*NRG1 fusion* Solid tumors Advanced/Metastatic (No standard/acceptable treatment)	MCLA-128	•Locally-advanced unresectable or metastatic solid tumor malignancy with documented NRG1 gene fusion •Patients must have received prior standard therapy or would be unlikely to tolerate or benefit from appropriate SOC or no satisfactory alternative treatment options are available • Patient with asymptomatic or stable brain metastases	A Phase I/II Study of MCLA-128, a full length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors
Roche BO41932 Phase II https://clinicaltrials.gov/ct2/show/NCT04589845	*NTRK1/2/3, ROS1, ALK, AKT, PIK3CA, BRAF II/III, RET* Solid tumors Advanced/Metastatic Subsequent line	Entrectinib, Alectinib, Atezolizumab, Ipatasertib, Trastuzumab Emtansine, GDC-0077	• Histologically or cytologically confirmed advanced or metastatic solid tumors •Disease progression on prior treatment, previously untreated disease with no available acceptable treatment •Any anticancer treatment > 2weeks prior to start of study treatment •Whole brain radiotherapy >14 days or stereotactic radiosurgery >7days prior to start of study treatment	Tumor-Agnostic Precision Immuno-oncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

SOLID TUMOR

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Relay RLY-4008-101 Phase I https://clinicaltrials.gov/ct2/show/NCT04526106	*FGFR2 alterations* Cholangiocarcinoma and Solid Tumors Advanced/Metastatic (No standard/acceptable treatment)	RLY-4408	• Histologically/cytologically confirmed unresectable or metastatic solid tumor with documented FGFR2 gene fusion, mutation, or amplification • Disease refractory to standard therapy, had not adequately responded to standard therapy • No ongoing, clinically significant FGFRi-induced retinal detachment or ongoing corneal or retinal disorder • Patient with asymptomatic CNS metastases or primary CNS tumor	A First-in-Human Study of Highly Selective FGFR2 Inhibitor, RLY-4008, in Patients With Intrahepatic Cholangiocarcinoma (ICC) and Other Advanced Solid Tumors
Rain Therapeutics (3202) Phase II https://clinicaltrials.gov/ct2/show/NCT05012397	*Wild-type (WT) TP53 and MDM2* Solid Tumors Advanced/Metastatic (No standard/acceptable treatment)	Milademetan (RAIN-32)	• Histologically and/or cytologically confirmed locally advanced/metastatic solid tumors with presence of Wild type TP53 and MDM2 gene amplification • Received all standard therapy and would be intolerant or benefit from standard therapy • No prior treatment with MDM2 inhibitor • No well-differentiated/dedifferentiated liposarcoma or initial sarcoma • No h/o primary brain tumor (e.g., glioma) • Patient with treated brain metastases	A Phase 2 Basket Study of Milademetan in Advanced/Metastatic Solid Tumors
Day One DAY 101-102 Phase II https://clinicaltrials.gov/ct2/show/NCT04985604	*BRAF Fusions, CRAF/RAF1 Fusions and Amplifications* Melanoma, Solid tumors Subsequent line	DAY101	• Patients must have histologically confirmed diagnosis of tumor with concurrent MAPK pathway alteration • Patient must have radiographically-recurrent or radiographically-progressive disease • Stable and treated brain metastases • No known presence of concurrent activating mutation • Patient with no current evidence or h/o central serous retinopathy (CSR), retinal vein occlusion (RVO) • No prior therapy with BRAF, MEK or MAPK directed inhibitor therapy • No prior receipt of any pan-RAF inhibitor therapy (e.g., LXH254/naporafenib, BGB- 283, BGB-3245, belvarafenib)	A Phase 1b/2, Open Label Study of DAY101 Monotherapy or Combination with Other Therapies for Patients with Recurrent, Progressive, or Refractory Solid Tumors and MAPK Pathway Aberrations

SOLID TUMOR

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
Pyramid Biosciences PBI-200-101 Phase I/II https://clinicaltrials.gov/ct2/show/NCT04901806	*NTRK-fusion positive or NTRK amplified, EWSR1-WT1-fusion-positive* Solid tumors Advanced/Metastatic (No standard/acceptable treatment)	PBI-200	For Phase 1, • NTRK-gene amplified, locally advanced or metastatic solid tumor EWSR1-WT1-positive DSRCTs. • Subjects with NTRK-fusion-positive solid tumors other than primary brain tumors must have previously received treatment with a TRK inhibitor, or the subject has declined treatment • Subjects with NTRK-gene amplified solid tumors, primary brain tumors or EWSR1-WT1-positive DSRCTs may have received prior treatment with a TRK inhibitor but this is not required. For Phase 2, • Has measurable disease by RECIST v1.1 for non-brain primary tumors or RANO criteria for subjects with primary brain tumors. • Subjects with non-brain primary tumors must have previously received treatment with a TRK inhibitor and a documented resistance mutation(s) (e.g., solvent front, gatekeeper or xDFG mutation). •Subjects with primary brain tumors may have received prior treatment with a TRK inhibitor but this is not required.	PBI-200-101 A Phase 1/2 Study of PBI-200 in Subjects with NTRK-Fusion-Positive Advanced or Metastatic Solid Tumors
Endeavor ENV-ONC-101 Phase II https://clinicaltrials.gov/ct2/show/NCT05199584	*PTCH1 mutations* Solid tumors (No standard/acceptable treatment)	ENV-101	•Histologically or cytologically confirmed advanced solid tumor that harbors a PTCH1 loss of function mutation • Patients must be refractory to all standard of care therapy, or standard or curative therapy does not exist, or the patient has documented their refusal of standard of care therapies	A Phase 2, Multi-Center Study Evaluating the Safety and Efficacy of ENV-101 (Taladegib) in Patients with Advanced Solid Tumors Harboring PTCH1 Loss of Function Mutations

SOLID TUMOR

CANCER & BLOOD SPECIALITY CLINIC

CARIS				
Research Study	**Indication & Line of Therapy**	**Intervention**	**Key Criteria**	**Protocol Title**
AADI Bioscience TSC-007 Phase II https://clinicaltrials.gov/ct2/show/NCT05103358	*TSC1; TSC2 alteration* Solid tumors Advanced/Metastatic (No standard/acceptable treatment)	ABI-009 nab-sirolimus	• Locally advanced or metastatic solid tumor with a pathogenic inactivating TSC1 or TSC2 alteration. • Patients must have received all standard therapies, unlikely to tolerate or derive clinically meaningful benefit from appropriate standard of care therapy, or the patient has no satisfactory alternative treatments. • No Prior treatment with an mTOR inhibitor, including nab-sirolimus • Patients with no primary brain tumors or PEComa	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
Apollomics, Inc APL-101-01 Phase II https://clinicaltrials.gov/ct2/show/NCT03175224	*c-Met Exon 14-skip mutation* Solid tumors Advanced/Metastatic Subsequent line	APL-101	• For Phase 2, five cohorts will be enrolled. Cohort A-1: NSCLC EXON 14 skip mutation (c-Met naïve) for first line treatment; Cohort A-2: NSCLC EXON 14 skip mutation (c-Met naïve) pretreated subjects with no more than 3 lines of prior therapy, Cohort B: NSCLC EXON 14 skip mutation (c-Met experienced; radiographic progression on prior c-Met inhibitor), Cohort C: basket of tumor types with c-Met high level amplification (except Primary CNS tumors), Cohort C-1: NSCLC harboring MET amplification and wild-type EGFR with no more than 3 lines of prior therapy (MET Naive), Cohort D: basket of tumor types except for primary CNS tumors harboring MET gene fusions (e.g., NSCLC, upper GI, colorectal, hepatobiliary cancer). Previously treated; or previously untreated but refused standard treatment, or if treatment was unavailable or unfeasible (≤ 3 prior lines). Met naive, Cohort E: Primary CNS tumors with MET alterations (single or co-occurred MET fusion including PTPRZ1-MET [ZM] fusion, MET Exon 14 skipping mutation, or MET amplification).Previously treated or previously untreated but refused standard treatment, or if treatment was unavailable or unfeasible (≤ 3 prior lines), Met naive. • No Known actionable mutation/gene rearrangement of EGFR (except for Cohort C), ALK, ROS1, RET, NTRK, KRAS, and BRAF	A Phase 1/2 Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects with Non-Small Cell Lung Cancer with c-Met EXON 14 Skip Mutations and c-Met Dysregulation Advanced Solid Tumors