

BREAST CANCER

<p>2/3 line Advanced mBC</p>	<p>Open label Bria-IMT w CPI (retifanlimab) cyclophosphamide and Interferon vs physicians choice (Carboplatin, Taxane, Capecitabine, Gemcitabine, Vinorelbine, Eribulin or HER2 agents: <i>Trastuzumab, Perjeta, Morgenza, Tukysa, Nerlynx, Tykreb</i>)</p>	<p>Briacell: BC-IMT-043: INCLUSION: Have histological confirmation of breast cancer with either locally recurrent unresectable and/or metastatic lesions, and have failed prior therapy:</p> <p>a. Patients with persistent disease and local recurrence must not be amenable to local treatment for patients with metastatic disease, late-stage MBC with no meaningful alternative therapies available and the following class specific treatment histories: a. Human epidermal growth factor 2 (HER2) positive must be previously treated with at least 3 regimens containing at least two anti-HER2 and at least one chemotherapy containing regimen.</p> <p>b. Estrogen receptor (ER), progesterone receptor (PR) positive tumors: must be refractory to hormonal therapy demonstrated by progression on at least 2 hormonal agents in 2 separate lines of hormone directed therapy.</p> <p>c. Triple Negative tumors: Must have exhausted all curative intent therapies including at least 2 prior chemotherapy regimens, which can include regimens in neoadjuvant and adjuvant settings.</p> <p>d. Cancers with known germline or genomic actionable targets, e.g. g/mBRCA, must have been treated with all tumor directed indicated treatment e.g. PARPi, if tolerated.</p> <p>e. HER2 low patients, in addition to the appropriate therapies based on ER/PR status and germline or genomic actionable targets, must also have received at least one HER2-targeted agent approved for treatment of HER2 low patients.</p> <p>f. HER2 negative tumors must be refractory to hormonal therapy (if indicated) and previously treated with at least 2 chemotherapy regimens.</p> <p>g. Patients with new or progressive breast cancer metastatic to the brain will be eligible provided: The brain metastases must be clinically stable (without evidence of progressive disease by imaging for at least 4 weeks prior to first dose)</p>	<p>Phase III UCLA/TRIO UCLA PI: Mccan PI: RP SC: Maria/ Nicole</p>
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Lung Cancer		
1st line squamous NSCLC	EIK1001 + SOC (pembrolizumab, Paclitaxel, Pemetrexed, Carboplatin)	<p>Eikon EIK1001-005: Inclusion: histologically confirmed NSCLC (Squamous) candidate for standard therapy with pembrolizumab and chemotherapy. Has confirmation that mutation-directed therapy is not indicated, measurable disease, has not received prior systemic treatment for advanced/ met NSCLC. prior neoadjuvant/adjuvant treatment >1 year after last dose are eligible. ECOG 0-1</p> <p>Exclusion: small cell elements, treatment within 4 weeks of IP, major surgery, >30 Gy within 6 months of IP, GI disorders, any other malignancy within 5 years, known active CNS mets or carcinomatous meningitis, hypersensitivity to pembro, carbo, paclitaxel or pemetrexed, active infection including pneumonitis HBV, HVC, heart conditions: CHF, QTcF >470ms at baseline</p>
First line Stage IV NSCLC with KRAS G12C-mutant and PDL1 TPS ≥ 50%	Double-blind MK 1084 + Pembrolizumab	<p>MERCK MK1084-004: Inclusion: Stage IV NSCLC with KRAS G12C and PDL1 ≥ 50% assessed by central laboratory (archival or fresh tissue must be available not previously irradiated). Measurable disease per RECIST 1.1, Life expectancy of at least 3 months, ECOG 0-1 w/in 7 days before randomization. adequate organ function</p> <p>Exclusion: uncontrolled comorbidity, inflammatory bowel disease requiring immunosuppressive medications, active neurological paraneoplastic syndrome, active infections, congestive heart failure, angina, QTcF >470ms, and/or other serious cardiovascular diseases within 6 months of study intervention, unable to swallow orally administered medication, or GI disorder affecting absorption, prior systemic anticancer therapy for mNSCLC, received prior anti-PD-L1, or anti-PD-L2 agent or other CTLA-4, OX-40, CD137, immunodeficiency or chronic systemic steroid therapy. psychiatric or substance abuse.</p>

Phase II
CBCC/Private
PI:RP
SC: Maria/Nicole

Phase III
CBCC/Private
PI: RP
SC: Nicole/Maria

<p>Stage IV or unsectable NSCLC who are tx naïve non-squamous or squamous w MTAP deletion</p>	<p>ARM A: AMG193 +carbo+paclitaxel+ pembro ARM B: AMG193 + carbo+pemetrex+p ebro ARM C: AMG193 +pembro</p>	<p><u>AMGEN 2023167: Inclusion:</u>Stage IV or unresectable NSCLC squamous or non-squamous eitology without prior systemic therapy, known PDL1 status TPS 1-50% or ≥50% locally or central lab, homozygous MTAP deletion by NGS testing, Archival Tissue within 5years, tissue biopsy may be obtained if archive tissue is unavailable, Recisit v1.1 measurable disease. Exclusion: Prior sytemic tx for metastatic NSCLC, major surgery radiotherapy within 28 days prior to fist dose, prior tx with MAT2A inhibitor or PRMT5 inhibitor, prior grade ≥2 immune-mediated AEs, known Actional mutations: ALK or EGFR, untreated sympomatic CNS mets or 2cm lesions of brain, uncontrolled pleural effusions, other malignancies w/in 3years, active infection, thrombosis w/in 6months, myocardial infact w/in 12months of enrollment, history of bowel obstruction, abdominal fistula, gi perforation, or abdominal abcess w/in 6months of study entry, positive HIV active infection, active Hepatitis B or C infection by PCR</p>	<p>Phase Ib TRIO-US UCLA PI: Goldman PI:RP SC: Nicole/Maria</p>
<p>PANCREATIC CANCER</p>			
<p>metastatic pancreatic cancer with MTAP-deletion without prior treatment</p>	<p>AMG 193 + gemcitabine+ nab-paclitaxel vs AMG 193 + mFOLFIRINOX</p>	<p><u>AMGEN 20230223: Inclusion:</u> MTAP-deletion mutation, measurable disease per Recist 1.1, ECOG 0-1, adaaquate organ function, archival tissue w/in 5 years, no other malignancies w/in 3 years, tissue biopsy may be obtained if archive tissue is unavailable. Exclusion: major surgery, radiotherapy within 28 days prior to fist dose, prior tx with MAT2A inhibitor or PRMT5 inhibitor,untreated sympomatic CNS mets or 2cm lesions of brain, uncontrolled pleural effusions</p>	<p>Phase Ib TRIO US UCLA PI: Wainberg PI:RP SC: Nicole/Maria</p>

SOLID TUMORS

Metastatic solid tumors to which no soc is available or intolerant to SOC therapy	single agent GIM-531 W or W/OUT anti - PD1	<u>GEORGIMUNE GIM531-CT01</u>: INCLUSION: solid tumors Currently enrolling (NSCLC, Ovarian, and Melanoma) with cytologically or histological confirmed locally advanced metastatic solid tumor that has progressed on SOC or for which no SOC therapies exist; or to be intolerant of SOC therapy, life expectancy ≥3months; ECOG 0-, Archival tissue available for central testing or a fresh tissue core needle biopsy, must have measurable disease. EXCLUSION: Brain mets, cardiopulmonary disease, structural cardiac disease, QTcF>470msec on baseline ECG, active autoimmune disease, melanoma with documented BRAF mutation.	Phase I/II CBCC Private PI: RP SC: Nicole/Maria
Metastatic Solid tumors to which no SOC is available or intolerant to SOC therapy	single agent AT-1965 IV	Alysum AT1965-101: Inclusion: (PART A) unresectable metastatic solid tumor that is refractory to standard therapy or for which in the opinion of the investigator no standard therapy is suitable. Measurable disease per RECIST 1.1 ECOG 0-1 adequate organ function, (PART B) TNBC received 2 prior lines of tx with a taxane and sacituzumab or irinotecan-hr for metastatic disease, TNBC with PDL1 or BRCA mutation need to have FDA approved therapies before participation in expansion cohort. Exclusion: no GI disorders that may affect absorption of study treatment, no cardiac disorders or uncontrolled medical condition, not history of autoimmune disease, interstitial lung disease, hemolytic anemia or hemolysis anemia, high LDH, Cushing syndrome or adrenal gland disorder, known HIV or HEP B OR C no solid tumor CNS, liquid/hematological tumors, lymphomas, uveal melanoma infection, LVEF <50% at baseline	Phase I/II CBCC Private PI: RP SC: Nicole/Maria

Colorectal

<p>treatment-naïve metastatic or unresectable adeno Left-sided Colorectal Cancer with KRAS or NRAS mutation and BRAFV600, Wild-type genomic findings</p>	<p>amivantamab + chemotherapy (mFOLFOX or FOLFIRI) vs cetuximab + chemotherapy (mFOLFOX or FOLFIRI)</p>	<p>Janssen 61186372COR3001 Origami-2: Inclusion: unresectable metastatic adenocarcinoma of the <u>left-sided colorectal cancer</u>; Left-sided CRC is defined as primary tumor that involves the splenic flexure, descending colon, sigmoid colon, rectosigmoid, or rectum. diagnosis must include WT for KRAS/NRAS G12 and G13, and BRAF V600 codons. Other KRAS/NRAS codons, as well as MSI-H/dMMR and ERBB2/HER2 amplification status should be determined per local guidelines and standard practice. ECOG 0-1. Must agree to the submission of Fresh tumor tissue Biopsy for Central analysis, fresh tumor tissue for participants who received neoadjuvant, adjuvant therapy or both. Measurable disease per Recist 1.1. Exclusion: <12months neo/adjuvant therapy, uncontrolled diabetes, active infection, participants are excluded if known mutation in the following codons: KRAS/NRAS A59, Q61, K117, or A146 or BRAF V600, Carcinoma of the anal canal is excluded.</p>	<p>Phase III TRIO-US UCLA PI: Hecht PI: RP SC: Nicole/Maria</p>
<p>Recurrent or unresectable or metastatic KRAS/NRAS with BRAF Wild-type Colorectal Cancer</p>	<p>amivantamab + FOLFIRI vs Cetuximab/Bevacizumab + FOLFIRI</p>	<p>Janssen 61186372COR3002 Origami-3: Inclusion: Participant must have received 1 line of systemic therapy for mCRC, with documented radiographic disease progression on or after this line of therapy. The regimen must be fluoropyrimidine-based and oxaliplatin-based therapy. Prior anti-VEGF therapy is allowed according to local regulatory approvals and SoC guidelines. recurrent unresectable metastatic of the colon or rectum with KRAS, NRAS, and BRAF WT tumor as determined by local testing. Both tissue- and blood-based testing is an acceptable method for the eligibility determination. WT for KRAS/NRAS G12 and G13 and BRAF V600 codons. Other KRAS/NRAS codons, as well as MSI-H/dMMR status and ERBB2/HER2 amplification status, should be determined per the local guidelines and standard practice. A participant is excluded from the study if the participant is known to have a mutation (with the exception of a silent mutation) in any of the following codons based on local testing: KRAS/NRAS G12, G13, A59, Q61, K117, or A146 or BRAF V600. ECOG PS of 0 or 1 Exclusion: Carcinoma of the anal canal is excluded.</p>	<p>Phase III TRIO-US UCLA PI: Hecht PI: RP SC: Nicole/Maria</p>