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PANONCOLOGY TRIALS

Enrolling Studies Quick Reference Guide

MULTIPLE SOLID TUMORS (NCT04123366)

Study Agents: Pembrolizumab + Olaparaib (PARP inhibitor)

Key Inclusion:

- Metastatic and/or unresectable solid tumor that is not eligible for curative treatment and for which standard of care has failed.
- Failed at least 1 previous line of therapy
- Life expectancy of 3months
- Has at least 1 mutation of the tumor of the following: BRACA1, BRACA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L.

MULTIPLE SOLID TUMORS (NCT03821935)

Study Agents: GARP-inhibitor + anti-PD1 agent

Key Inclusion:

- Advanced solid tumor who are considered refractory to or intolerant of all existing therapy, or who are considered ineligible for standard therapies.
- Histologically confirmed triple negative breast cancer [TNBC], pancreatic adenocarcinoma, urothelial cancer, hepatocellular carcinoma, or head and neck squamous cell carcinoma.
- TNBC, pancreatic adenocarcinoma and HCC must be treatment naïve to immunotherapy.
- TNBC must have disease progression during or after at least 1 systemic therapy that included a taxane in the metastatic or recurrent setting.
- Pancreatic adenocarcinoma who have disease progression during or after 1 systemic therapy (gemcitabine monotherapy or in combination, FOLFIRINOX [or another regimen including both 5-FU and oxaliplatin], capecitabine monotherapy or in combination) administered in the adjuvant, locally advanced, or metastatic setting.
- Urothelial cancer of the bladder and urinary tract must have progressed following treatment with a platinum-based regimen (administered in any line of therapy) and a PD1/PDL1 antagonist administered in the recurrent or metastatic setting (progression is defined as unequivocal progression on or within 3 months of the last dose of anti-PD1 or anti-PDL1 therapy).
- Advanced HCC who have disease progression during or after 1 prior line of systemic therapy. Child-Pugh score of 7 or less. Subjects with hepatitis B virus (HBV) infection are required to be receiving effective antiviral therapy, but subjects with hepatitis C virus (HCV) RNA level must be undetectable.
- Advanced/metastatic HNSCC (from the oral cavity, oropharynx, hypopharynx, or larynx) who have progressed following treatment with a platinum-based regimen (administered in any line of therapy) and PD1/PDL1 antagonist administered in the recurrent or metastatic setting (progression defined as unequivocal progression on or within 3 months of the last dose of anti-PD1 or anti-PDL1 therapy.)

PROSTATE (NCT04100018)

Study Agents: Nivolumab +Docetaxel + Prednisone vs. Docetaxel + Prednisone alone

Key Inclusion:

- Adenocarcinoma of the prostate
- Evidence of stage IV disease as defined by American Joint Committee on Cancer (AJCC)
- Ongoing ADT with a gonadotropin-releasing hormone (GnRH) analogue or bilateral Orchiectomy confirmed by testosterone level ≤ 1.73 nmol/L (50 ng/dL).
- Documented prostate cancer progression as within 6 months prior to screening by increase of PSA (by 2 risings) or more than 2 bone lesions or pelvic lymph nodes measuring at least 2cm.
- Chemotherapy- naïve for mCRPC and have received at least 1 but no more than 2 second-generation hormonal manipulations (novel antiandrogen therapies [NAT] eg, including abiraterone acetate, enzalutamide, apalutamide, and darolutamide) in the recurrent non-metastatic setting and/or the metastatic setting no more than 1 NAT.
- Biopsy within 1 year prior to enrollment date.
- Naïve to anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody.
- Naïve to docetaxel or another chemotherapy agent for mCRPC. Prior docetaxel allowed if 12 months elapsed from last dose.

COLORECTAL CA (NCT04008030)

Study Agents: Nivolumab vs Nivolumab + Ipilimumab vs Chemotherapy of choice (FOLFOX; FOLFOX + bevacizumab; FOLFOX + cetuximab; FOLFIRI; FOLFIRI + bevacizumab; FOLFIRI + cetuximab)

Key Inclusion:

- Microsatellite Instability High (MSI-H) or Mismatch Repair Deficient (dMMR)
- Have not received anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibod Tx.

COLORECTAL CA (NCT04094688)

Study Agents: FOLFOX or FOLFIRI + Bevacizumab + Vitamin D3

Key Inclusion:

- Histologically confirmed locally advanced/metastatic colorectal adenocarcinoma with no planned metastasectomy with No dMMR or MSI-H disease
- No prior systemic treatment for metastatic disease
- Prior rectal chemoradiation permitted
- Is not supplementing with Vitamin D >= 2,000 IU per day over 12 months

COLORECTAL CANCER (NCT04264702) *Surveillance Study*

Key Inclusion:

- Have surgically resected adenocarcinoma of the colon or rectum
- Pathologic stage II or III disease non metastatic
- Clinically eligible for chemotherapy

GASTRIC CA (NCT04318080)

Study Agents: Tislelizumab + Oxaliplatin or Cisplatin/5FU with Capecitabine vs Oxaliplatin or Cisplatin/5FU with Capecitabine alone

Key Inclusion:

- Locally Advanced Unresectable or Metastatic Gastric or GEJ Adenocarcinoma
- Have not received previous systemic therapy or have been up to more than 6 months without treatment.
- Patients with Her2(-), PD-L1(+) *PD-L1 done at BeiGene Lab*

HEAD & NECK SQUAMOUS CELL CA (NCT03071757)

Study Agents: anti-PD1 + 0X40 [Tumor necrosis factor] agent

Key Inclusion:

- Recurrent HNSCC and is locally advanced or metastatic to oral cavity, oropharynx, hypopharynx, and/or larynx.
- Previously received platinum-based therapy.

- Treatment naïve to anti-PD-1/PD-L1-based therapy

NON-SMALL CELL LUNG CANCER (NCT03649971)

Study Agents: Lazertinib + JNJ-61186372 [EGFR inhibitor +EGFR-cMet antibody] agent

Key Inclusion:

- NSCLC with previously identified EGFR mutation (by Local Lab) that is metastatic or unresectable and have progressed after standard of care front-line therapy.
- Have progressed on Osimertinib (Tagrisso) and platinum-based doublet chemotherapy (Cisplatin, Carboplatin or Nedaplatin + one of the following paclitaxel, docetaxel, gemcitabine, vinorelbine, and irinotecan)
- Have EGFR mutations or T790M mutation (depends on the cohort) (EGFR exon19 deletion or L858R)
- No history of interstitial lung disease (ILD)

NON-SMALL CELL LUNG CANCER (NCT04487080)

Study Agents: Amivantamab + Lazertinib vs Osimertinib alone vs Lazertinib alone

Key Inclusion:

- NSCLC locally advanced or metastatic not amenable to curative therapy that has been histologically or cytologically confirmed.
- Previously determined to have EGFR Exon 19del or Exon 21 L858R substitution. The biopsy must have been obtained at or after the diagnosis of advanced disease.
- Treatment naïve or has not received adjuvant or neoadjuvant therapy for the past 12 months.
- Treatment naïve to EGFR tyrosine kinase inhibitors (TKI's).
- No history of Interstitial Lung Disease/pneumonitis.

NON-SMALL CELL LUNG CANCER (NCT03906071)

Study Agents: MRTX849 alone [KRAS G12C inhibitor] vs Docetaxel alone

Key Inclusion:

- Histologically confirmed diagnosis of NSCLC with KRASG12C mutation.
- Receipt prior treatment with a platinum (cisplatin or carboplatin) and an immune anti-PD-1/PD-L1 inhibitor concurrently or sequentially for advanced or metastatic disease with the outcome of objective disease progression on or after treatment
- Treatment naïve to agent targeting KRAS G12C (e.g., AMG510)

ADVANCED NON-SMALL CELL LUNG CANCER (NCT04077463)

Study Agents: Lazertinib + Human Bispecific EGFR and cMet Antibody

Key Inclusion:

- Histologically or cytologically confirmed metastatic or unresectable EGFR mutated (EGFR exon 19 deletion or L858R) NSCLC
- Progressed after SOC front-line therapy and exhausted available options with targeted therapy
- Prior use of platinum-doublet chemotherapy in adjuvant or neo-adjuvant setting allowed if < 12 months.
- No antiPD-1 or antiPD-L1 therapy within 6 weeks of dosing

SOLID TUMORS WITH KRAS MUTATION (NCT03785249)

Study Agents: MRTX849 alone [KRAS G12C inhibitor]

Key Inclusion:

- Histologically confirmed diagnosis of solid tumor malignancy with KRAS G12C mutation as squamous or non-squamous NSCLC or adenocarcinoma of the colon or rectum that is unresectable or metastatic.
- Treatment naïve to KRASG12C inhibitor (e.g., AMG510).
- For NSCLC, the patients must have previously received treatment with at least a platinum-containing chemotherapy regimen and checkpoint inhibitor therapy.
- For NSCLC there must no EGFR or ALK genetic tumor aberrations.
- For CRC, it must be histologically confirmed, and the patient may had received treatment with

cetuximab in accordance with the ERBITUX® USPI and may or may not have demonstrated tumor positivity for EGFR-expression.

NON-SMALL CELL LUNG CANCER & BASKET TUMOR TYPES (ANCT03175224)

Study Agents: APL-101 [c-Met receptor]

Key Inclusion:

- Histologically and / or cytological confirmed unresectable or metastatic solid malignancy, refractory to standard therapies with no more than three prior lines of therapy.
- Non-Small-Cell Lung Cancer with EXON 14 skip mutations and are c-Met naïve, c-Met experienced or Radiographic progression on prior c-Met inhibitor.

Note: For Non-Small-Cell Lung Cancer it includes all histologies.

- Basket of tumor types with c-Met highlevel amplification or -Met fusions.

Note: For basket tumor it needs to be naïve to c-Met inhibitors (including crizotinib, capmatinib, savolitinib).

Note: c-Met fusions including the following, but not limited to: BAIAP2L1-MET; C8orf34-MET; CAPZA2-MET; DCTN1-MET; EPS15-MET; LRRFIP1-MET; METMET; OXR1-MET; PPFIBP1-MET; PTPRZ1-MET; TFG-MET; TPR-MET; TRIM4-MET; ZKSCAN1-MET; KIF5B-MET and any other known c-Met activating mutations.

LEUKEMIA (NCT04102020)

Study Agents: Venetoclax + Azacitidine + Best supportive care vs Best supportive care alone

Key Inclusion:

- Newly diagnosed AML.
- No history of Acute promyelocytic leukemia (APL)
- Confirmed CR or CRi following completion of planned induction and consolidation chemotherapy
- Achieved first CR or CRi within 4 months of enrollment or be no more than 75 days since last dose
- AML has intermediate or adverse risk cytogenetics per NCCN
- Not a candidate for allogeneic stem cell transplantation

MYELODYSPLASTIC SYNDROME (NCT04401748)

Study Agents: Venetoclax + Azacitidine vs Azacitidine alone

Key Inclusion:

- Higher-risk Myelodysplastic Syndrome (< 20% bone marrow blasts per bone marrow biopsy/aspirate) and is Treatment-Naïve
- Hematopoietic stem cell transplant (HSCT) eligible with no pre-arranged HSCT at the time of Study or HSCT ineligible without plan for HSCT at the time of Study
- No previous diagnosis of therapy-related MDS (t-MDS), MDS due to pre-existing myeloproliferative neoplasm (MPN) and MDS/MPN including chronic myelomonocytic leukemia (CMML), atypical chronic myeloid leukemia (aCML), juvenile myelomonocytic leukemia (JMML) and unclassifiable MDS/MPN.

CLASSICAL HODGKIN LYMPHOMA (NCT04318080)

Study Agents: Tislelizumab

Key Inclusion:

- Histologically confirmed diagnosis of relapsed or refractory cHL.
- Relapsed cHL (disease progression after PR or CR to the most recent therapy) or refractory cHL (failure to achieve PR or CR to most recent therapy).
- Has NOT received an autologous hematopoietic stem cell transplant (HSCT) and is not a candidate for another one or has failed to achieve a response or progressed after autologous HSCT and after brentuximab vedotin
- Or is relapsed or refractory to salvage chemotherapy, including brentuximab and vedotin without prior autologous or allogeneic HSCT.
- Or has received at least 2 prior systemic chemotherapy regimens and failed to achieve a response or progressed after brentuximab vedotin

- Treatment naïve to PD-1 or PD-L1, anti-PD-L2, or anti CTLA-4 agent.
- Do NOT have diagnosis of nodular lymphocyte-predominant Hodgkin lymphoma or gray zone lymphoma.
- Has NOT received prior allogeneic hematopoietic stem cell transplantation.

INTERMEDIATE HEPATOCELLULAR CA (NCT04340193)

Study Agents: Nivolumab + Ipilimumab vs Nivolumab alone vs Ipilimumab alone

Key Inclusion:

- Histologically confirmed intermediate-stage HCC by BCLC staging.
- No prior TACE (trans-arterial embolization)
- Naïve for HCC chemotherapy, immune therapy (anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody), and targeted kinase inhibitors.
- No prior treatment with radioactive isotope yttrium (Y90).
- Tumor characteristics that exceed the BMU7 criteria (Number of nodules + diameter of largest nodule = 7)
- No EHS, no regional lymph node involvement, no main, left main, or right main portal vein thrombosis, and no VI. (Segmental bland portal vein thrombosis is allowed).
- Child-Pugh score 5-6
- Tumor tissue obtained within 3 months prior to randomization.
- If HBV-HCC, or HCV-HCC infection must be resolved.
- No ascites or history of ascites.

ADVANCED HEPATOCELLULAR CA (NCT04039607)

Study Agents: Nivolumab + Ipilimumab vs Sorafenib or Lenvatinib alone

Key Inclusion:

- Histologically confirmed advanced HCC of any etiology and is not eligible for curative surgical and/or locoregional therapies or has progressed after them.
- Have not received previous systemic anticancer therapy for unresectable/advanced HCC.
- Child-Pugh score 5 or 6
- Have NOT been diagnosed with fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC.
- Does NOT have clinically significant ascites defined as prior ascites that required treatment and require on-going prophylaxis, OR current ascites requiring treatment
- No presence of portal hypertension with hx.. of bleeding due to esophageal or gastric varices within 6 months
- No active co-infections of Hepatitis and HIV.

BLADDER CA (NCT04241185)

Study Agents: Pembrolizumab + CRT (Cisplatin, 5-FU + MMC or Gemcitabine) vs. CRT alone

Key Inclusion:

- Has clinically non-metastatic muscle invasive bladder cancer (T2-T4aN0M0) * **Note:** If mixed histology and eligible the urothelial component of ≥50% must be provided.
- Is eligible for bladder preservation and willing to receive Chemoradiotherapy
- Had a TURBT performed within 60 days prior to enrollment
- Do not have a diffusive carcinoma in situ (multiple foci of CIS) throughout the bladder nor neuro-endocrine tumors
- Treatment naïve for MIBC.

BLADDER CA (NCT03288545)

Study Agents: Enfortumab Vedotin monotherapy vs. EV and Pembrolizumab

Key Inclusion:

- Advanced/Metastatic Bladder Cancer ineligible to receive cisplatin (GFR < 60 mL/min or ECOG = 2)
- Muscle Invasive Bladder Cancer in the Neoadjuvant setting use of Enfortumab Vedotin and pembrolizumab vs. EV alone for those undergoing cystectomy.

- No previous anti-PDL1 or PD1 therapy

ADVANCED/METASTATIC OR INOPERABLE CHOLANGIOCARCINOMA (NCT03773302)

Study Agents: Infigratinib

Key Inclusion:

- Histologically or cytologically confirmed unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 gene fusions/translocations
- MEK or selective FGFR inhibitor naïve
- Unresectable locally advanced or metastatic cholangiocarcinoma systemic anti-cancer therapy naïve, except if disease recurrence ≥ 6 months after last therapy
- No history of liver transplant

UROTHELIAL CARCINOMA (NCT04197986)

Study Agents: Infigratinib (anti-FGFR3)

Key Inclusion:

- Histologically or cytologically confirmed, invasive urothelial carcinoma with susceptible FGFR3 alterations within 120 days of nephroureterectomy, distal ureterectomy, or cystectomy.

Note: FGFR3 gene is mutated in Exon 7 (R248C, S249C), Exon 10 (G370C, A391E, Y373C), or Exon 15 (K650M/T, K650E/Q). FGFR3 gene fusion or translocation allowed if evidenced.

- If post neoadjuvant, pathologic stage at surgical resection must be ypT2 and/or yN+. Neoadjuvant therapy is defined as at least 3 cycles of cisplatin-based chemotherapy with a planned cisplatin dose of 70 mg/m2/cycle.

Note: Patients who received less than this or non-cisplatin-based neoadjuvant treatment will be considered as having received no neoadjuvant chemotherapy.

- If required adjuvant therapy, patient must be ineligible to receive cisplatin-based chemotherapy
- Must have a centrally reviewed negative postoperative CT (defined as lymph nodes with short axis <1.0 cm and no metastatic disease at baseline)
- Treatment naïve to MEK or selective FGFR inhibitor
- NO presence of positive surgical margins
- NO BCG or other intravesical therapy for NMIBC within the previous 30 days.

RENAL CELL CANCER (NCT03793166)

Study Agents: Ipilimumab + Nivolumab + cabozantinib/VEGF inhibitor

Key Inclusion:

- Histologic documentation of renal cell carcinoma with clear cell component with metastatic disease.
- Intermediate or poor risk per IDMC criteria.
- No prior treatment with PD-1, PD-L1, or CTLA-4 targeting agents.
- No prior previous systemic therapy for renal cell carcinoma (prior HD IL-2 (>28 days) and prior adjuvant sunitinib >180 days since completion are allowed).
- Is not under Warfarine or Xa inhibitors treatment

GENITOURINARY CANCERS (NCT04094688)

Study Agents: Ipilimumab + Nivolumab + cabozantinib/VEGF inhibitor

Key Inclusion:

- Histology confirmed small cell carcinoma of the bladder, adenocarcinoma of the bladder, squamous cell carcinoma of the bladder, plasmacytoid urothelial carcinoma, sarcomatoid renal cell carcinoma, sarcomatoid urothelial carcinoma of the bladder, renal medullary carcinoma, or bone only disease.
- Metastatic disease defined as new or progressive lesions on cross-sectional imaging or bone scan.
- Patients may have received any number of prior anti-cancer treatments or be treatment naïve (with the exception of patients with small cell carcinoma of the bladder, whom should have received a platinum-based combination regimen either as neoadjuvant, adjuvant or first-line treatment
- No concomitant treatment with warfarin nor Xa inhibitors.
- Naïve to cabozantinib, but prior treatment with MET or VEGFR inhibitors is allowed. However prior MET or VEGF and prior PD-1/PD-L1/CTLA-4 (sequentially or in combination) are not allowed.