CMOH OPEN TRIALS AS OF SEPTEMBER 2020:
CONTACT BECKI BANAS FOR PATIENT SCREENING OR ANY ADDITIONAL TRIAL INFORMATION
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IMMEDIATE ENROLLMENT AVAILABLE

BREAST

18247 ELACESTRANT MONOTHERAPY VS. STANDARD OF CARE FOR THE TREATMENT OF PATIENTS WITH ER+/HER2- ADVANCED BREAST CANCER FOLLOWING CDK4/6 INHIBITOR THERAPY: A PHASE 3 RANDOMIZED, OPEN-LABEL, ACTIVE-CONTROLLED, MULTICENTER TRIAL(EMERALD)(RAD1901-308

- subjects must have er+/her2-tumor status
- subjects must have previously received at least one and no more than two lines of endocrine therapy for advanced/metastatic breast cancer
- subjects must have received prior treatment with a cdk4/6 inhibitor in combination with either fulvestrant or an aromatase inhibitor (ai).
- subjects may have received no more than one line of chemotherapy in the advanced/metastatic setting.

14059 PHASE II TRIAL OF IBRUTINIB PLUS TRASTUZUMAB IN HER2-AMPLIFIED METASTATIC BREAST CANCER

- progression of disease on or within 6 months of completing prior t-dm1 therapy
- ≤4 prior chemotherapy regimens for mbc (phase i portion) or ≤3 prior chemotherapy

17079 MAMMAPRINT, BLUEPRINT, AND FULL-GENOME DATA LINKED WITH CLINICAL DATA TO EVALUATE NEW GENE EXPRESSION PROFILES: AN ADAPTABLE REGISTRY (FLEX REGISTRY)

- new breast cancer diagnosis

CLL

18263 A PHASE 2, MULTICENTER, SINGLE-ARM STUDY OF ZANUBRUTINIB (BGB-3111) IN PATIENTS WITH PREVIOUSLY TREATED CHRONIC LYMPHOCYTIC LEUKEMIA/SMALL LYMPHOCYTIC LYMPHOMA INTOLERANT OF PRIOR TREATMENT WITH IBRUTINIB (BGB-3111-215)

- documented failure to achieve at least partial response (pr) or documented disease progression after response to the most recent treatment regimen. refractory disease is defined as treatment failure (stable disease, non-response, progressive disease [pd]) or disease progression within 6 months after the most recent prior therapy (hallek et al, 2008).

19084 A SINGLE-ARM, EXPANDED ACCESS STUDY OF ZANUBRUTINIB (BGB-3111) IN PATIENTS WITH RELAPSED/REFRACTORY (R/R) MANTLE CELL LYMPHONA (BGB-3111-216)

- histologically confirmed diagnosis of (r/r) mantle cell lymphona disease or treatment-naive and considered by their treating physician to be unsuitable for standard chemoimmunotherapy regimens

19182 A PROSPECTIVE, OPEN-LABEL, MULTICENTER RANDOMIZED PHASE III TRIAL TO COMPARE THE EFFICACY AND SAFETY OF A COMBINED REGIMEN OF OBINUTUZUMAB AND VENETOCLAX VERSUS FLUDARABINE, CYCLOPHOSPHAMIDE AND RITUXIMAB (FCR)/ BENDAMUSTINE AND RITUXIMAB (BR) IN FIT PATIENTS WITH PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WITHOUT DEL (17P) OR TP53 MUTATION (CO41685)

- have previously untreated documented chronic lymphocytic leukemia (cll) according to the international workshop on chronic lymphocytic leukemia (iwcll) criteria cll requiring treatment according to the iwcll criteria

LUNG

19018 A RANDOMIZED PHASE 3 STUDY OF SITRAVATINIB IN COMBINATION WITH NIVOLUMAB VERSUS DOCETAXEL IN PATIENTS WITH ADVANCED NON-SQUAMOUS NON-SMALL CELL LUNG CANCER WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY AND CHECKPOINT INHIBITOR THERAPY (SAPPHIRE)

- histologically confirmed non-squamous nsclc with metastatic or unresectable, locally advanced disease, not amenable to treatment with curative intent.
- receipt of prior first-line treatment in the advanced disease setting with a platinum-based chemotherapy regimen in combination with a cit (i.e., anti-pd-1 or anti-pd-l1 including nivolumab, pembrolizumab, or atezolizumab), with the result of radiographically documented progression of disease on or after the combination regimen.
- first-line treatment may have included maintenance therapy with a chemotherapy agent (e.g., pemetrexed) and/or a cit. duration of treatment on prior cit at least 4 months.
- most recent prior therapy (e.g., chemotherapy, cit, or radiation therapy) discontinued at minimum of 2 weeks before the date of first on-study treatment.
- candidacy to receive treatment with docetaxel as the next line of therapy if randomized to the comparator arm.

20142 EFFICACY, SAFETY OF TECENTRIQ COMBINATION WITH CABOMETYX COMPARED WITH DOCETAXEL MONOTHERAPY IN PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER PREVIOUSLY TREATED WITH AN IMMUNE CHECKPOINT INHIBITOR AND PLATINUM-BASED CHEMOTHERAPY

PROSTATE

19144 METASTATIC PROSTATE FOR OUR BIOMARKER DATA TRIAL – NO DRUG- DATA TRIAL- LOOKING FOR GENE MUTATIONS IN PROSTATE

SOLID TUMOR

20186 TUMOR-AGNOSTIC PRECISION IMMUNO-ONCOLOGY AND SOMATIC TARGETING RATIONAL FOR YOU (TAPISTRY) PHASE II PLATFORM-*More to come*

UROTHELIAL

19032BIOMARKER STUDY TO IDENTIFY SUBJECTS WITH ADVANCED UROTHELIAL CANCER AND FIBROBLAST GROWTH FACTOR RECEPTOR GENE ABERRATIONS (42756493BLC0002)

- transitional cell carcinoma of the urothelium.
- minor components (less than [<] 50 percent overall) of variant histology are acceptable.
- diagnosis of either: a.) metastatic or surgically unresectable urothelial cancer (uc) (stage iv), b.) localized surgically-resectable or resected uc with a t classification of t2 or above who are at high risk for progression to advanced disease as assessed by the investigator.
- available archival tissue sample for fibroblast growth factor receptor (fgfr) aberration analysis. the archived tissue must either be from 1) metastatic site, 2) localized uc specimen that includes muscle invasive disease (t2 or above).
- eastern cooperative oncology group performance status of 0 to 2.

Abington Hematology Oncology Associates

CMOH Consultants in Medical Oncology and Hematology

STAR TRIALS: 3-4 WEEKS FOR ENROLLMENT

19154-ANAL, BILIARY, BLADDER, BONE METS, BRAIN, BREAST, CERVICAL, COLON, ENDOMETIAL, FALLOPIAN TUBE, GALL BLADDER CANCER, GASTRIC, EAD and NECK, KAPOSIS, KIDNEY, LUNG, OVARIAN, PANCREATIC, PENILE, PERITONEAL, PROSTATE, RECTAL, RENAL, SARCOMA, SOLID TUMOR, TESTICULAR, THYROID, UROTHELIAL, UTERINE, VAGINAL, VULVAR

19154 MULTIPLE EXPANSION COHORT TRIAL OF MRTX849 in PATIENTS WITH ADVANCED SOLID TUMORS WITH KRAS G12C MUTATION

- Histologically Confirmed Diagnosis of a solid tumor malignancy with KRAS G12C mutation
- Unresectable or Metastatic Disease
- Standard Treatment is not available or patient declines
- Cannot have active Brain metastases
- No history of intestinal disease or major gastric surgery

18264 BILIARY, GALL BLADDER

18264 A PHASE 3 MULTICENTER, OPEN-LABEL, RANDOMIZED, CONTROLLED STUDY OF ORAL INFIGRATINIB VERSUS GEMCITABINE WITH CISPLATIN IN SUBJECTS WITH ADVANCED/METASTATIC OR INOPERABLE CHOLANGIOCARCINOMA WITH FGFR2 GENE FUSIONS/TRANSLOCATIONS: THE PROOF TRIAL (QBGJ398-301)

- histologically or cytologically confirmed non-resectable, recurrent or metastatic cholangiocarcinoma.
- participants with gallbladder cancer or ampulla of vater carcinoma are not eligible.
- must not have received treatment with any systemic anti-cancer therapy for unresectable, recurrent, or metastatic cholangiocarcinoma. prior neoadjuvant or adjuvant therapy is permitted if completed > 6 months prior to first dose of study drug.

20172-BLADDER, ENDOMETRIAL, UROTHELIAL

20172 ENFORTUMAB VEDOTIN AS MONOTHERAPY OR IN COMBINATION WITH OTHER ANTICANCER THERAPIES FOR THE TREATMENT OF UROTHELIAL CANCER

- Histologically documented Ia/mUC, including squamous differentiation or mixed cell types

BREAST

19054 RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY OF TUCATINIB OR PLACEBO IN COMBINATION WITH ADO-TRASTUZUMAB EMTANSINE (T-DM1) FOR SUBJECTS WITH UNRESECTABLE LOCALLY-ADVANCED OR METASTATIC HER2+ BREAST CANCER (HER2CLIMB-02) (SGNTUC-016)

- histologically confirmed her2+ metastatic breast carcinoma as determined by a sponsor-designated central laboratory
- history of prior treatment with a taxane and trastuzumab in any setting, separately or in combination
- have progression of unresectable la/m breast cancer after last systemic therapy, or be intolerant of last systemic therapy

19171 ESSENTIAL THROMBOCYTHEMIA, MYELOFIBROSIS

19171 A RANDOMIZED, CONTROLLED PHASE 3 STUDY OF PACRITINIB VERSUS PHYSICIAN'S CHOICE IN PATIENTS WITH PRIMARY MYELOFIBROSIS, POST POLYCYTHEMIA VERA MYELOFIBROSIS, OR POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS WITH SEVERE THROMBOCYTOPENIA (PLATELETS COUNTS <50,000/µL) (PAC203)

- pmf, ppv-mf, or pet-mf (as defined by tefferi and vardiman 2008) dipss intermediate-1, intermediate -2, or high risk (passamonti et al 2010)
- prior ruxolitinib treatment with failure to benefit or intolerance as defined by at least one of the following:
    - treatment for ≥3 months with inadequate efficacy response defined as <10% spleen volume reduction by mri or <30% decrease from baseline in spleen length by physical examination or regrowth to these parameters following an initial response; and/or
    - treatment for ≥28 days complicated by either: development of a red blood cell transfusion requirement (at least 2 units/month for 2 months) **or** national cancer institute (nci) ctcae grade ≥3 aes of thrombocytopenia, anemia, hematoma, and/or hemorrhage while being treated with a dosage of <20 mg bid
- palpable splenomegaly ≥5 cm below the lower costal margin in the midclavicular line as assessed by physical examination

LUNG:

18129 BRIGATINIB-3001- A PHASE 3 RANDOMIZED OPEN-LABEL STUDY OF BRIGATINIB (ALUNBRIG®) VERSUS ALECTINIB (ALECENSA®) IN ADVANCED ANAPLASTIC LYMPHOMA KINASE-POSITIVE NON–SMALL-CELL LUNG CANCER PATIENTS WHO HAVE PROGRESSED ON CRIZOTINIB (XALKORI®) -ALK+

- have histologically or cytologically confirmed stage iiib (locally advanced or recurrent) or stage iv non-small cell lung cancer (nsclc).
- must meet one of the following criteria: *have documentation of anaplastic lymphoma kinase (alk) rearrangement by a positive result from the vysis alk break-apart fluorescence in situ hybridization (fish) probe kit or the ventana alk (d5f3) cdx assay or foundation medicine's foundation one cdx. *have documented alk rearrangement by a different test and be able to provide tumor sample to the central laboratory. (note: central laboratory alk rearrangement testing results are not required to be obtained before randomization).
- had progressive disease (pd) while on crizotinib, as assessed by the investigator or treating physician. (note: crizotinib does not need to be the last therapy a participant received. the participant may have received chemotherapy as his/her last therapy).

19208 A RANDOMIZED, OPEN-LABEL, PHASE 3 STUDY OF PRALSETINIB VERSUS STANDARD OF CARE FOR FIRST LINE TREATMENT OF RET FUSION-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER (BLU-667-2303)

- patient has pathologically confirmed, definitively diagnosed, advanced (not able to be treated with surgery or radiotherapy) or metastatic nsclc and has not been treated with systemic anticancer therapy for metastatic disease.
- patient must have a documented ret-fusion

19239: DOUBLE BLIND STUDY OF THE GLUTAMINASE INHIBITOR TELAGLENASTAT WITH PEMBROLIZUAB AND CHEMOTHERAPY VESUS PLACEBO WITH PEMBROLIZUMAB AND CHEMOTHERAPY IN FIRST LINE METASTATIC KEAP1/NRF2 MUTATED NONSQUAMOUS, NONSMALL CELL LUNG CANCER

- Stage IV disease not previously treated with systemic therapy for metasttic NSCLC. Patients who received adjuvant or neoadjuvant therapy with or without immunotherapy for localized NSCLC are eligible if all adjuvant/neoadjuvant therapy Iincluding immunotherapy) was completed at least 6 months prior to the development of metastatic disease
- Mutation KEAP1or NRF2 documented by NGS and STK11/LKB1 mutation is known for the purpose of stratification

LYMPHOMA: HODGKINS and NON HODGKINS:

11282 (SGN35-015) A PHASE 2 OPEN-LABEL STUDY OF BRENTUXIMAB VEDOTIN IN FRONT-LINE THERAPY OF HODGKIN LYMPHOMA (HL) AND CD30-EXPRESSING PERIPHERAL T-CELL LYMPHOMA (PTCL) IN OLDER PATIENTS OR PATIENTS WITH SIGNIFICANT COMORBIDITIES INELIGIBLE FOR STANDARD CHEMOTHERAPY

- treatment-naive patients with histopathological diagnosis of classical hodgkin lymphom
- treatment-naive patients with cd30-expressing

HODGKIN'S:

18013 SGN35-027: MULTIPLE PART CLINICAL TRIAL OF BRENTUXIMAB VEDOTIN (INCLUDING NIVOLUMAB) IN CLASSICAL HODGKIN LYMPHOMA SUBJECT

- treatment-naïve, Hodgkin lymphoma (hl) patients with Ann arbor stage 3 or 4 disease

Abington Hematology Oncology Associates

CMOH Consultants in Medical Oncology and Hematology

PROSTATE:

16238 TRITON3: A MULTICENTER, RANDOMIZED, OPEN-LABEL PHASE 3 STUDY OF RUCAPARIB VERSUS PHYSICIAN'S CHOICE OF THERAPY FOR PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER ASSOCIATED WITH HOMOLOGOUS RECOMBINATION DEFICIENCY (CO-338-063)

- experienced disease progression after having received 1 prior next generation androgen receptor-targeted therapy for castration-resistant disease
- have a deleterious mutation in a brca1/2 or atm gene
- no prior treatment with any parp inhibitor
- no prior treatment with chemotherapy for mcrpc.

18103 A PHASE 3 RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF NIRAPARIB IN COMBINATION WITH ABIRATERONE ACETATE AND PREDNISONE VERSUS ABIRATERONE ACETATE AND PREDNISONE FOR TREATMENT OF SUBJECTS WITH METASTATIC PROSTATE CANCER (64091742PCR3001)

- no systemic therapy (that is, novel second-generation ar-targeted therapy such as enzalutamide, apalutamide, or darolutamide; taxane-based chemotherapy, or more than 4 months of abiraterone acetate plus prednisone [aa-p] prior to randomization) in the metastatic castration-resistant prostate cancer (mcrpc) setting; or aa-p outside of the mcrpc setting

18128- CYCLONE TRIAL: DOUBLE BLIND, PLACEBO CONTROLLED STUDY OF ABIRATERONE ACETATE PLUS PREDNISONE WITH OR WITHOUT ABEMACICLIB IN PATIENTS WITH METASTATIC CASTRATION RESISTANT PROSTATE CANCER

- Metastatic prostate cancer documented by positive bone scan and/or measurable soft tissue metastatic lesions by CT or magnetic resonance imaging
- Progressive disease at study entry demonstrated during continuous androgen deprivation therapy post orchiectomy
- Be able and willing to undergo mandatory tumor biopsy of at least one metastatic site

SKIN:

18014 CX-4945 ADMINISTERED ORALLY TWOICE DAILY TO PATIENTS WITH ADVANCED BASAL CELL CARCINOMA

SOLID TUMORS:

19079 (INCB 54828-207) A PHASE 2, OPEN-LABEL, SINGLE-ARM, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PEMIGATINIB IN PARTICIPANTS WITH PREVIOUSLY TREATED LOCALLY ADVANCED/METASTATIC OR SURGICALLY UNRESECTABLE SOLID TUMOR MALIGNANCIES HARBORING ACTIVATING FGFR MUTATIONS OR TRANSLOCATIONS (FIGHT-207)

- histologically or cytologically confirmed solid tumor malignancy that is advanced or metastatic or is surgically unresectable.
- radiographically measurable disease (per recist v1.1 or rano for primary brain tumors).
- tumor lesions located in a previously irradiated area or in an area subjected to other loco-regional therapy are considered measurable if progression has been clearly demonstrated in the lesion.
- documentation of an fgfr1-3 gene mutation or translocation.
- objective progression after at least 1 prior therapy and no therapy available that is likely to provide clinical benefit. participants who are intolerant to or decline the approved therapy are eligible only if they have no therapy available that is likely to provide clinical benefit.

19092 A PHASE 2 STUDY OF ERDAFITINIB IN SUBJECTS WITH ADVANCED SOLID TUMORS AND FGFR GENE ALTERATIONS (42756493CAN2002)

- histologic demonstration of an unresectable, locally advanced, or metastatic solid tumor malignancy with a fibroblast growth factor receptor (fgfr) mutation or fgfr gene fusion
- measurable disease
- participant must have received at least one prior line of systemic therapy in the metastatic setting
- documented progression of disease, defined as any progression that requires a change in treatment, prior to full study screening

SOLID TUMORS:

18164 A PHASE 1/2 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 (BLU-667-1101)

- group 1 - patients must have pathologically documented, definitively diagnosed locally advanced or metastatic nsclc with a ret rearrangement that was previously treated with a multi-kinase inhibitor (mki) that inhibits ret, such as cabozantinib, lenvatanib, vandetanib, ponatinib, sorafenib and alectinib.
- group 2 - patients must have pathologically documented, definitively diagnosed locally advanced or metastatic nsclc with a ret rearrangement that was not previously treated with a mki.
- group 3 - patients must have pathologically documented, definitively diagnosed advanced mtc that has progressed within 14 months prior to the screening visit and was previously treated with a mki.
- group 4 - patient must have pathologically documented, definitely diagnosted advanced mtc that has progressed within 14 months prior to the screening visit and was not previously treat with a mki.
- group 5 -patients must have a pathologically documented, definitively diagnosed advanced solid tumor with an oncogenic ret rearrangement/fusion or mutation, other than nsclc and mtc.
- GROUP 6 - PATIENT MUST HAVE A PATHOLOGICALLY DOCUMENTED, DEFINITELY DIAGNOSED ADVANCED SOLID TUMOR WITH AN ONCOGENIC RET REARRANGEMENT/FUSION OR MUTATION THAT WAS PREVIOUSLY TREATED WITH A PREVIOUS SELECTIVE TKI THAT INHIBITS RET

UROTHELIAL:

19094 QBGJ398-302: PHASE 3, MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL OF INFIGRATINIB FOR THE ADJUVANT TREATMENT OF SUBJECTS WITH INVASIVE UROTHELIAL CARCINOMA WITH SUSCEPTIBLE FGFR3 GENETIC ALTERATIONS (PROOF302)

- have histologically or cytologically confirmed, invasive urothelial carcinoma with susceptible fgfr3 alterations within 120 days following nephroureterectomy, distal urethrectomy, or cystectomy
- if the patient received neoadjuvant chemotherapy, pathologic stage at surgical resection must be ajcc stage ≥ypt2 and/or yn+.
- if the patient did not receive neoadjuvant chemotherapy:
  a.must be ineligible to receive cisplatin-based adjuvant chemotherapy per the galsky criteria:
  - creatinine clearance < 60cc/min or
  - ≥grade 2 hearing loss or
  - ≥grade 2 neuropathy)
  b.pathologic stage must be ajcc stage ≥pt2 pn0-2 m0 (post-lymphadenectomy or no lymphadenectomy [pnx]) for upper tract disease.
  c.pathologic stage should be ajcc stage ≥pt3 or pn+ (bladder cancer).

17133 THOR STUDY: PHASE 3 STUDY OF ERDAFITINIB COMPARED WITH VINFLUNINE OR DOCETAXEL OR PEMBROLIZUMAB IN SUBJECTS WITH ADVANCED UROTHELIAL CANCER AND FGFR GENE ABERRATIONS

- Metastatic or surgically unresectable urothelial cancer
- Documented progression of disease, defined as a progression that requires a change in treatment prior to randomization