MERCY
MEDICAL CENTER

ACTIVE CANCER CLINICAL TRIALS
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Clinical Trials Nurses

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New Addition

- S1609 DART- reactivation – cohort 30 Chordoma
- EA5161 - Randomized Phase II Clinical Trial of Cisplatin/Carboplatin and Etoposide (CE) alone or in Combination with Nivolumab as Frontline Therapy for Extensive Stage Small Cell Lung Cancer (ED-SCLC)

Closures

- S1400I – Permanent Closure - A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (Lung-MAP Sub-Study)
- S1403 – Permanent Closure - A Randomized Phase II/III Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer
- A071102 – Permanent Closure - accrual met – Testing Temozolomide with Veliparib Or Placebo In Specific Patients with Newly Diagnosed Glioblastoma Multiforme
- S1609 DART- Temporary Closure – cohort 27 Dermoid tumors
- S1609 DART- Temporary Closure – cohort 37 Gastrointestinal stromal tumor
- S1609 DART- Temporary Closure – cohort 17 Epithelial tumors of penis
- S1609 DART- Temporary Closure – cohort 8 Pancreatic tumor including acinar cell carcinoma
- S1609 DART- Temporary Closure – cohort 24 Pheochromocytoma, malignant
- S1609 DART- Temporary Closure – cohort 36 Metaplastic carcinoma (of the breast)
- S1609 DART- Temporary Closure – cohort 6 Squamous cell carcinoma with variants of GI tract
- S1609 DART- Permanent Closure – cohort 5 Adenocarcinoma with variant of small intestine
- S1609 DART- Temporary Closure – cohort 33 Not Otherwise Categorized (NOC) Rare Tumors
- S1416 Temporary Closure – Main cohort- Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, with or Without Metastases

RARE AND/OR CANCER OF UNKNOWN PRIMARY

Rare or Unknown Primary S1609

A list of **eligible rare histologies is located at the back of this clinical trials list.*

***Ineligible** rare histologies: anal, lymphoma, merkel cell, pleural mesothelioma, sarcoma, thymic, uterine leiomyosarcoma*

Nivolumab (240mg q 2 wks) + Ipilimumab (1 mg/kg q 6 wks)

BREAST CANCER

The ABC Trial: Adjuvant Therapy for Node Positive HER2 Negative Stage II or III Breast Cancer A011502

Aspirin (300 mg/d) x 5 yrs vs Placebo x 5 yrs

Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes After Neoadjuvant Chemotherapy S1418

- Patients with weekly ER or PR positive by IHC are eligible if considers not eligible for adjuvant endocrine therapy
- Patients must complete adjuvant chemotherapy, if given, prior to starting pembrolizumab

Observation vs MK-3475(pembrolizumab) IV followed by surgery
(200mg q3w for 52wks)

Early breast ca <12 mos, Her-2 Neg, chemo & surgery completed, BMI ≥ 27 ..... A011401

2 year health education vs 2 year health education + supervised weight loss intervention

Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer ..... SWOG S1416

Main cohort temporarily closed to accrual

Cisplatin day1 + Placebo PO BID days 1-14 every 21 days vs Cisplatin day1 + ABT-888 PO BID days 1-14 every 21 days

Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer NRG-BR003

AC *then* weekly paclitaxel x12 doses q2wks x 4 cycles *vs* AC *then* weekly paclitaxel + carboplatin x12 doses auc5 q3wks x 4 cycles q2wks x 4 cycles

Stage I-III breast cancer receiving anastrozole, Asian and Native Hawaiian/Pacific Islanders ..... ECOG E1Z11

Anastrozole 1mg daily *then* No AIMSS: f/u q3 mos, with PRO, up to 1 yr

vs

AIMSS: treatment at discretion of physician

Continue/discontinue drug, treat AIMSS, ≤ 6 wk holiday, switch AI, tamoxifen, or treatment trial

If discontinuation, PRO, *then* f/u 1 mo, PRO

HER2+ invasive breast cancer with brain mets ..... RTOG 1119

WBRT vs WBRT + oral lapatinib

COLON

Stage III colon adenocarcinoma with presence of deficient DNA MisMatch Repair via IHC A021502

Randomized into arm 1 or arm 2 with the following treatment/surgery plan:

Arm 1: mFOLFOX6 Plus Atezolizumab 840mg IV

12 cycles of mFOLFOX6, 12 months (25 cycles) of atezolizumab, starting on Day 1 Cycle 1 of mFOLFOX6

Vs.

Arm 2: mFOLFOX6

Phase III Metastatic Colorectal 1st Line Tx with Deficient DNA Mismatch Repair……..…..NRG-GI004/SWOG S1610 – COMMIT

***Will request approval from NCI CIRB upon patient eligibility**-SIV with PI and RN along with electronic delegation log required*

Arm 1: mFOLFOX6/bevacizumab

Arm 2: Atezolizumab monotherapy 840 mg IV on Day 1 of every cycle

Arm 3: mFOLFOX6/bevacizumab/atezolizumab

Phase III trial for Stage 0-III colorectal who completed resection and chemoXRT ……..S0820 - PACES
Patients must be registered between 180 days and 456 days of resection.
Patients need pure tone audiometry evaluation to document air conduction within 30 days prior to registration.
eflornithine placebo 2 tablets Oral Daily and sulindac placebo 1 tablet Oral Daily for 3 years
or
eflornithine 2 tablets Oral Daily and sulindac 1 tablet Oral Daily for 3 years

RECTAL

Locally advanced rectal planning sphincter-sparing surgery .....Alliance N1048 - PROSPECT
Randomized into group 1 or 2 with the following treatment/surgery plan:
Group 1: FOLFOX q 2 wks x 6 (without radiation)
If regression ≥ 20% then surgery: LAR with Total Mesorectal Excision
(If regression < 20%, then 5FUCMT followed by surgery)
R0 then FOLFOX x 6 cycles (suggested)
R1 & R2 5FUCMT & FOLFOX x 4 cycles (suggested)
vs
Group 2: *5FU or Capecitabine* (Oncologist choice) + radiation therapy
Then LAR with Total Mesorectal Excision
Then FOLFOX x 8 cycles (suggested)
Patient withdraws from study if progressive disease at any time.

Locally advanced rectal with the major portion of the tumor intact..... NRG-GI002
Temporarily closed to accrual
FOLFOX6 x 8 cycles *then* RT (4500 cGy 25 over 5 wks) + Capecitabine (825 mg/m2 po bid on RT days)
vs
FOLFOX6 x 8 cycles *then* RT (4500 cGy 25 over 5 wks) + Capecitabine (825 mg/m2 po bid on RT days) + Veliparib (400mg po bid thru RT)

Phase III Metastatic Colorectal 1st Line Tx with Deficient DNA Mismatch Repair……..NRG-GI004/SWOG S1610 – COMMIT
Will request approval from NCI CIRB upon patient eligibility-*SIV with PI and electronic delegation log required before opening*
Arm 1: mFOLFOX6/bevacizumab
Arm 2: Atezolizumab monotherapy 840 mg IV on Day 1 of every cycle
Arm 3: mFOLFOX6/bevacizumab/atezolizumab

Phase III trial for Stage 0-III colorectal who completed resection and chemoXRT ……..S0820 - PACES
Patients must be registered between 180 days and 456 days of resection.
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eflornithine placebo 2 tablets Oral Daily and sulindac placebo 1 tablet Oral Daily for 3 years
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eflornithine 2 tablets Oral Daily and sulindac 1 tablet Oral Daily for 3 years

RENAL

Metastatic or locally advanced papillary RCC not amenable to surgical resection, *Phase II*.....S1500
Will request approval from NCI CIRB upon patient eligibility.
Sunitinib vs Cabozantinib vs Crizotinib vs Savolitinib until progression

PROSTATE

Unfavorable intermediate or favorable high-risk prostate ca..... RTOG 0924
Neo-ad. Androgen deprivation therapy + prostate & seminal vesicle RT + boost to prostate & proximal seminal vesicles
vs
Neo-ad. Androgen deprivation therapy + whole-pelvic RT + boost to prostate & proximal seminal vesicles

Phase III postprostatectomy……NRG-GU003

Will request approval from NCI CIRB upon patient eligibility.

ARM I COPORT 66.6 Gy in 37 fractions of 1.8 Gy to the prostate bed; EQD2 (1.5 Gy) = 63 Gy

Vs.

ARM II HYPORT 62.5 Gy in 25 fractions of 2.5 Gy to the prostate bed; EQD2 (1.5 Gy) = 71 Gy

LYMPHOMA

Early relapsing or refractory Follicular Lymphoma grade I, II or IIIa, *Phase II*.....…….S1608

Will request approval from NCI CIRB upon patient eligibility

Mandatory tissue submission

Up to 12 cycles of Obinutuzumab 1000mg IV Day 1 plus either

Arm 1: TGR-1202 800 mg PO daily or Arm 2: Lenalidomide 20 mg PO days 1 -21 or Arm 3: CHOP IV Day 1 (up to 6 cycles)

HEAD AND NECK

Resected high-risk malignant salivary gland tumors ..... RTOG 1008

Will request approval from MMC IRB upon patient eligibility.

RT *(60-66 Gy in 2Gy daily fractions)* + Cisplatin *(40mg/m^2 wkly during RT x 7 doses)*

VS

RT *(60-66 Gy in 2Gy daily fractions)*

MDS

National MDS Study..... ECOG NHLBI-MDS

Physician training required when patient presents (needs done before consent or registration)

Suspected MDS or MDS/MPN overlap disorders and undergoing diagnostic work-up with planned bone marrow assessments

or

Diagnosed with de novo or therapy-related MDS within 6-months of enrollment undergoing clinical evaluation and planned bone marrow assessments to confirm MDS or to evaluate disease status

Observational Study with Specimen Acquisition

MELANOMA

Unresectable Stage III/IV melanoma, may have received prior adj systemic therapy, tested for BRAF status ..... ECOG EA6141

Phase II/III

Suspension as of 6/23/17 for planned interim analysis

Ipilimumab investigator training required

Nivolumab + Ipilimumab + Sargramostim x 4 cycles (1mg/kg d1; 3mg/kg d1; 250ug sq d1-14)

then maintenance *up to 2 yrs**:***

Nivolumab + Sargramostim (3mg/kg d1; 250ug sq d1-14)

vs

Nivolumab + Ipilimumab x 4 cycles (1mg/kg d1; 3mg/kg d1)

then maintenance *up to 2 yrs:*

Nivolumab (3mg/kg d1)

MULTIPLE MYELOMA

Newly dx symptomatic multiple myeloma – *Phase II* .....ECOG E1A11

Physician to perform birth control portion of consent

FISH testing must be done ≤ 90 days prior to registration; Step 0 pre-registration bone marrow aspirate and slides submission required

Induction:

Bortezomib (1.3mg/m^{2}SQ or IV) + Lenalidomide (25mg PO) + Dexamethasone (PO) (q 3wks x 12)

then

Maintenance:

Lenalidomide (15mg PO) (q 4 wks x 24) *then* observation

vs

Carfilzomib (20mg/m^{2}IV cycle 1; 36mg/m^{2}IV cycle s 2-9) + Lenalidomide (25mg PO) + Dexamethasone (PO) (q 4wks x 9)

Lenalidomide (15mg PO) (q 4wks) until progression or excessive toxicity

NON-SQUAMOUS NSCLC

Ongoing management for lung nodule or newly dx NSCLC with smoking hx ..... OncoCyte PRO068

1. Willing to donate blood for biomarker research at Mercy
2. Prior to XRT, chemo and/or surgery
3. Will receive $25 Target gift card

Resectable, Stage IB (≥ 4 cm), II(A or B) or IIIA non-squamous NSCLC ..... ALCHEMIST

Register to screening trial Alliance A151216: FFPE tissue submitted for EGFR and ALK genotyping

then

EGFR Mutation - register to trial Alliance A081105

Erlotinib (150 mg/day up to 2 yrs) vs Observation (prior to 6/15/17, this arm is placebo)

ALK Rearrangement - register to trial ECOG E4512

Crizotinib (250 mg po BID up to 2 yrs) vs Observation (prior to 6/15/17, this arm is placebo)

EGFR/ALK Wildtype, Prior Surgical Resection and Adjuvant Chemo –

register to trial ECOG EA5142*(pending ECOG approval & training)*

Nivolumab (240mg IV q2 weeks up to 1 year) vs Observation per standard of care

Stage IV pt who can consent to review of medical records and complete mo. phone calls about their quality of life …OSU BLCIO

AIM 1 (Period between study Initiation to 6 months): Observational Phase telephone surveys for 2 years patient reimbursed $15 each survey completed

AIM 2: Randomized to free Advanced genomic and immunotherapy testing or usual standard of care with telephone surveys for 2 years

Repository: Optional to patients who agreed to participate in the main study to offer tissue and blood sample storage to OSU

MRA (diagnosed up to 1 year to initiation of the study): medical record arm ONLY

SQUAMOUS NSCLC

Resectable, Stage IB (≥ 4 cm), II(A or B) or IIIA squamous NSCLC ..... ALCHEMIST

Register to screening trial Alliance A151216: FFPE tissue submitted for EGFR and ALK genotyping

then

Prior Surgical Resection and Adjuvant Chemo – register to trial ECOG EA5142 *pending ECOG approval and training*

Nivolumab (240mg IV q2 weeks up to 1 year) vs Observation per standard of care

2nd line tx following platinum-containing chemo for NSCLC – *Phase II/III* ..... SWOG S1400

Pre-Screening/Screening Registration to determine known positive biomarker vs no known positive biomarker

Optional: S1400GEN ancillary study to evaluate patient & physician knowledge, attitudes, and preferences related to return of genomic results

Known Positive Biomarker:

- **HRRD *(S1400G)*:** Talazaparib (1000 mcg Oral qd)
- **C-MET *(S1400K):*** ABBV-399 (2.7 mg/kg IV Day 1 Every 21 days)

Non-Match, Anti-PD-1/PD-L1 Resistant (S1400F)

- MEDI4736 (Durvalumab) 1500mg IV plus Tremelimumab 75mg IV every 28 days for 4 cycles followed by MEDI4736 (Durvalumab) alone

Stage IV pt who can consent to review of medical records and complete mo. phone calls about their quality of life …OSU BLCIO

AIM 1 (Period between study Initiation to 6 months): Observational Phase telephone surveys for 2 years patient reimbursed $15 each survey completed

AIM 2: Randomized to free Advanced genomic and immunotherapy testing or usual standard of care with telephone surveys for 2 years

Repository: Optional to patients who agreed to participate in the main study to offer tissue and blood sample storage to OSU

MRA (diagnosed up to 1 year to initiation of the study): medical record arm ONLY

SMALL CELL LUNG

***Phase II Frontline Tx for Newly dx Extensive Stage SCLC** ..... ECOG EA5161

Treating physician choice between Cisplatin or Carboplatin and Etoposide with or without Nivolumab 360mg every 3 weeks for 4 cycles

Then followed by maintenance Nivolumab 240mg every 2 weeks up to 2 years for patients assigned to Arm A

S1609 – DART Eligible Rare Cancer Histologies

1. ***Temporary Closure*** - Epithelial tumors of nasal cavity, sinuses, nasopharynx
   A. Squamous cell carcinoma with variants of nasal cavity, sinuses, and nasopharynx and trachea (excluding laryngeal, nasopharyngeal cancer [NPC], and squamous cell carcinoma of the head and neck [SCCHN])
   B. Adenocarcinoma and variants of nasal cavity, sinuses, and nasopharynx.
2. ***Permanent Closure***- Epithelial tumors of major salivary glands
3. ***Temporary Closure*** - Salivary gland type tumors of head and neck, lip, esophagus, stomach, trachea and lung, breast and other location
4. Undifferentiated carcinoma of gastrointestinal (GI) tract
5. ***Permanent Closure*** - Adenocarcinoma with variants of small intestine
6. ***Permanent Closure*** - Squamous cell carcinoma with variants of GI tract (stomach small intestine, colon, rectum, pancreas)
7. ***Permanent Closure*** - Fibromixoma and low grade mucinous adenocarcinoma (pseudomixoma peritonei) of the appendix and ovary
8. ***Temporary Closure*** - Pancreatic tumor including acinar cell carcinoma, mucinous or serous cystadenocarcinoma
9. ***Permanent Closure*** - Intrahepatic Cholangiocarcinoma
10. ***Permanent Closure*** - Cholangiocarcinoma and extrahepatic bile duct tumors
11. Sarcomatoid carcinoma of lung
12. Bronchoalveolar carcinoma lung. This condition is now also referred to as adenocarcinoma in situ, minimally invasive adenocarcinoma, lepidic predominant adenocarcinoma, or invasive mucinous adenocarcinoma.
13. ***Permanent Closure*** - Non-epithelial tumors of the ovary
    A. Germ cell tumor of ovary
    B. Mullerian mixed tumor and adenosarcoma
14. Trophoblastic tumor
    A. Choriocarcinoma
15. Transitional cell carcinoma other than renal pelvis ureteral or bladder
16. ***Temporary Closure*** - Cell tumor of the testes and extragonadal germ tumors
    A. Seminoma and testicular sex cord cancer
    B. Non seminomatous tumor
    C. Teratoma with malignant transformation
17. ***Temporary Closure -***Epithelial tumors of penis - squamous adenocarcinoma cell carcinoma with variants of penis
18. Squamous cell carcinoma variants of the genitourinary (GU) system
19. Spindle cell carcinoma of kidney, pelvis, ureter
20. ***Temporary Closure -*** Adenocarcinoma with variants of GU system (excluding prostate cancer)
21. Odontogenic malignant tumors
22. ***Temporary Closure*** - Endocrine carcinoma of pancreas and digestive tract
23. ***Permanent Closure*** - Neuroendocrine carcinoma including carcinoid of the lung
24. ***Temporary Closure*** - Pheochromocytoma, malignant
25. Paraganglioma
26. ***Temporary Closure -*** Carcinomas of pituitary gland, thyroid gland parathyroid gland and adrenal cortex
27. ***Temporary Closure -*** Dermoid tumors
28. ***Temporary Closure -*** Peripheral nerve sheath tumors and NF1-related tumors
29. Malignant giant cell tumors
30. Chordoma
31. Adrenal cortical tumors
32. ***Permanent Closure*** - Tumor of unknown primary (Cancer of Unknown Primary; CUP)
33. ***Temporary Closure*** - Not Otherwise Categorized (NOC) Rare Tumors, after discussion with Study
34. ***Permanent closure -*** Adenoid cystic carcinoma
35. ***Temporary Closure -*** Vulvar Cancer
36. ***Temporary Closure*** - Metaplastic carcinoma (of the breast)
37. ***Temporary Closure -*** Gastrointestinal stromal tumor