ACTIVE CANCER CLINICAL TRIALS
September 2016

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Additions
S1416: 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

S1507: A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies

Changes
EAY131 – MATCH trial has been approved by the NCI CIRB and we are currently accruing patients to it.
MOLECULAR ANALYSIS FOR THERAPY CHOICE

Solid tumor or lymphoma that has progressed following at least one line of standard systemic therapy and/or for whose disease no standard treatment exists that has been shown to prolong survival, measurable disease; requires biopsy covered by trial.................................................................ECOG EAY131 – MATCH

Subprotocol A: Afatinib for Mutations of EGFR (Other Than Small Cell and NSCLC)
Subprotocol B: Afatinib for HER2 Activating Mutations
Subprotocol C1: Crizotinib for MET Amplification
Subprotocol C2: Crizotinib for MET Exon 14 Deletion
Subprotocol E: AZD9291 for EGFR T790M Mutations (Except NSCLC) or Rare Activating Mutations of EGFR
Subprotocol F: Crizotinib for ALK Rearrangements (Other Than Adenocarcinoma of Lung or ALCL)
Subprotocol G: Crizotinib for ROS1 Translocations (Other Than NSCLC)
Subprotocol H: Dabrafenib and Trametinib for BRAF V600E or V600K Mutations (Excluding Melanoma and Thyroid Cancer)
Subprotocol I: GDC-0032 (Taselisib) for PIK3CA but without KRAS Mutation or PTEN Loss (excluding breast cancer)
Subprotocol N: PI3K Beta Specific Inhibitor, GSK2636771, for PTEN Mutation or Deletion, with PTEN Expression on IHC
Subprotocol P: PI3K Beta Specific Inhibitor, GSK2636771, for PTEN Loss by IHC
Subprotocol Q: Ado-trastuzumab Emtansine in HER2 Amplification (Except Breast and Gastric/GEJ Adenocarcinomas)
Subprotocol R: Trametinib in BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations
Subprotocol S1: Trametinib for NF1 Mutations
Subprotocol S2: Trametinib for GNAQ or GNA11 Mutations
Subprotocol S2: Trametinib for GNAQ or GNA11 Mutations
Subprotocol T: GDC-0449 (Vismodegib) for Smoothened (SMO) or Patched 1 (PTCH1) Mutations (excluding basal cell skin carcinoma)
Subprotocol U: VS-6063 (defactinib) in Tumors with NF2 Loss
Subprotocol V: Sunitinib in c-Kit Mutations (Excluding GIST, Renal Cell Carcinoma or Pancreatic Neuroendocrine Tumor)
Subprotocol W: AZD4547 for Aberrations in the FGFR Pathway
Subprotocol X: Dasatinib for DDR2 Mutations
Subprotocol Y: AZD5363 for AKT Mutations
Subprotocol Z1A: Binimetinib with NRAS Mutations (Excluding Melanoma)
Subprotocol Z1B: Palbociclib for CCND1, 2, 3 Amplification
Subprotocol Z1D: Nivolumab for Mismatch Repair Deficiency (Excluding Colorectal Cancer)

BRAIN METS

Brain mets outside a 5mm margin around hippocampus ..............................................................NRG-CC001
Pending RT credentialing
WBRT 30 Gy/10 + Memantine vs WBRT with Hippocampal Avoidance using IMRT 30 Gy/10 + Memantine

BRAIN CANCER

Newly diagnosed grade IV intracranial glioblastoma or gliosarcoma .......................................................Alliance A071102
Pre-registration central pathology MGMT testing + Complete RT/TMZ
then
MGMT positive:
TMZ (150-200mg/m2) PO qd days 1-5

Veliparib/placebo (40mg) PO bid days 1-7 every 28 days x 6 cycles
MGMT negative: ineligible
BREAST CANCER

*** Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer .......................... SWOG S1416
Cisplatin day1 + Placebo PO BID days 1-14 vs Cisplatin day1 + ABT-888 PO BID days 1-14
every 21 days every 21 days

Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer .............................................. NRG-BR003
AC then weekly paclitaxel vs AC then weekly paclitaxel + carboplatin
q2wks x 4 cycles x12 doses q2wks x 4 cycles x12 doses auc5 q3wks x 4 cycles

Metastatic ER positive and Her2 negative .................................................................................................................. Alliance A011203
A biopsy of metastatic disease is required prior to enrollment
Post-menopausal women previously tx with aromatase inhibitor
Z-Endoxifen HCI (80 mg/day)
vs
Tamoxifen (20mg/day) then at progression Z-Endoxifen HCI (80mg/day)

Stage I-III breast cancer receiving anastrozole, Asian and Native Hawaiian/Pacific Islanders .................................. ECOG E1Z11
Anastrozole then No AIMSS: f/u q3 mos, with PRO, up to 1 yr
1mg daily 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

COLORECTAL

Any stage newly dx colorectal adenocarcinoma with dx in 2013-2016 ...................................................................... OSU OCCPI
Tissue submission for MSI + IHC +/- methylation – screening for Lynch Syndrome

Metastatic/advanced CRC, K-ras wild-type, after first-line tx with oxaliplatin-containing chemo and bevacizumab .ECOG E7208
Phase II MMC IRB review pending, upon patient eligibility – Can be expedited upon request.
Must have had prior first-line with oxaliplatin-based 5-FU chemo + bevacizumab for metastatic colorectal cancer
Irinotecan + Cetuximab every 2 wks vs Irinotecan + Cetuximab + Ramucirumab (IMC-1121B) every 2 wks
180mg/m² 500mg/m² vs 150mg/m² 400mg/m² 6mg/kg

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

RECTAL

Locally-advanced rectal .................................................................................................................................................. 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.

*** Denotes newly listed study
OVARIAN, PERITONEAL or FALLOPIAN TUBE

Recurrent or persistent epithelial ovarian, primary peritoneal or fallopian tube cancer, mucinous histology not eligible

Suspended and Pending PI protocol-specific training

Nivolumab then Nivolumab vs Nivolumab + Ipilimumab then Nivolumab
(3mg/kg) (3mg/kg) (1mg/kg) (3mg/kg)
q2wksx4 q2wks for max 42 doses q3wksx4 q3wksx4 q2wks for max 42 doses

PROSTATE

Castration resistant metastatic prostate

Enzalutamide vs Enzalutamide + Abiraterone + Prednisone
(160mg daily) (160mg daily) (1000mg daily) (5mg 2x daily)

Unfavorable intermediate or favorable high-risk prostate ca

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

HEAD AND NECK

Locally-advanced resected head and neck cancer -- Gross total resection of tumor; no prior chemo

T1, N1-2 or T2-4a, N0-2, M0
RT (2 Gy/day, in 30 fractions for total of 60 Gy)
Cetuximab then RT (as above) + Cetuximab then Cetuximab
(initial dose 400 mg/m²) (250 mg/m²/week x 6) (250 mg/m²/week x 4)

Resected high-risk malignant salivary gland tumors

Will request approval from MMC IRB upon patient eligibility.
RT (60-66 Gy in 2Gy daily fractions) + Cisplatin (40mg/m² weekly during RT x 7 doses)
vs
RT (60-66 Gy in 2Gy daily fractions)

MDS

National MDS Study

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

LYMPHOMA

Newly Dx diffuse large B-cell lymphoma, Phase II

Pending lenalidomide counselor training

Physician/counselor must take lenalidomide training, perform birth control portion of consent, re-counsel at least every 28 days
Lenalidomide + R-CHOP vs RCHOP
MELANOMA

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

**Phase II/III**

Ipilimumab investigator training required

| Nivolumab + Ipilimumab + Sargramostim x 4 cycles | vs | Nivolumab + Ipilimumab x 4 cycles |
| 1mg/kg | 3mg/kg | 250ug sq |
| dl | dl | d1-14 |

then maintenance up to 2 yrs:

| Nivolumab + Sargramostim |
| 3mg/kg |
| d1 |

MELANOMA

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 + Lenalidomide + Dexamethasone (q 3wks x 12) | vs | Carfilzomib + Lenalidomide + Dexamethasone (q 4wks x 9) |
| 1.3mg/m²SQ or IV | 25mg PO | PO |
| then |

Maintenance:

| Lenalidomide (q 4 wks x 24) then observation | vs | Lenalidomide (q 4wks) until progression or excessive toxicity |
| 15mg PO |

Smoldering multiple myeloma ≤ 60 months .............................................................................................................................................. ECOG E3A06

Physician/counselor must take lenalidomide training, perform birth control portion of consent, re-counsel at least every 28 days

**Pending lenalidomide counselor training**

| Lenalidomide (25mg d1-21) + Aspirin (days 1-28) | vs | Observation |

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

***Kras Mutation Positive NSCLC and Progressive Disease Following One or Two Prior Systemic Therapies .......... SWOG S1507***

| Trametinib (2mg d1-21) + Docetaxel (75 mg/m² d1) |

Stage IV or Recurrent NSCLC, EGFR mutation (exon 19 deletion or L858R) ...................................................................................... SWOG S1403

| Afatinib + Cetuximab | vs | Afatinib |

NSCLC and N₀ -- <2cm peripheral & outer third ............................................................................................................................... CALGB 140503

| Lobectomy | vs | Limited Resection |

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

Pending CTSU approval and training for EA5142

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 | Placebo (daily up to 2 yrs) |

**ALK Rearrangement - register to trial ECOG E4512**

| Crizotinib (250 mg po BID up to 2 yrs) | vs | Placebo (up to 2 yrs) |

**EGFR/ALK Wildtype, Prior Surgical Resection and Adjuvant Chemo – register to trial ECOG EA5142**

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

*** Denotes newly listed study
Unresectable Stage IIIA/B non-squamous NSCLC – Phase II ................................................................. RTOG 1306

Will request approval from MMC IRB upon patient eligibility.

EGFR TK Mutation Cohort:

Erlotinib (150 mg/day x 12 wks) then Standard Chemo*/RT vs Standard Chemo*/RT

ALK Tran L Cohort or EGFR + ALK Tran L:

Crizotinib (250 mg/bid x 12 wks) then Standard Chemo*/RT vs Standard Chemo*/RT

*Standard ChemoChoice: cisplatin + etoposide or paclitaxel + carboplatin weekly x6 followed by 2 cycles consolidation

Unresectable Stage IIIA/B NSCLC – Phase II ...................................................................................... NRG LU001

Metformin HCL not supplied by trial, but available from Mercy Pharmacy

Concurrent ChemoRT x 6 wks then Consolidation Chemo x 6 wks

vs

Metformin HCL (1000mg - 2000mg) qd x 2 wks

then

Concurrent ChemoRT + Metformin HCL (2000mg qd) x 6wks

then

Consolidation Chemo + Metformin HCL (2000mg qd) x 10 wks

SQUAMOUS NSCLC

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

Pending CTSU approval and training for EA5142

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

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

***Kras Mutation Positive NSCLC and Progressive Disease Following One or Two Prior Systemic Therapies........ SWOG S1507

Trametinib (2mg d1-21) + Docetaxel (75 mg/m2 d1)

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

No Known Positive Biomarker:

Nivolumab + Ipilimumab vs Nivolumab

(3mg/kg q 14days) (1mg/kg q 42 days) (3mg/kg q 14days)

Known Positive Biomarker:

• P13K: GDC-0032 (4mg daily)

• CDK4/6: Palbociclib (125mg daily [3 wks on / 1 wk off]) – arm temporarily suspended

• FGFR: AZD4547 (80mg BID daily)

Unresectable Stage IIIA/B NSCLC – Phase II ...................................................................................... NRG LU001

Metformin HCL not supplied by trial, but available from Mercy Pharmacy

Concurrent ChemoRT x 6 wks then Consolidation Chemo x 6 wks

vs

Metformin HCL(1000mg - 2000mg) qd x 2 wks

then

Concurrent ChemoRT + Metformin HCL (2000mg qd) x 6wks

then

Consolidation Chemo + Metformin HCL (2000mg qd) x 10 wks

*** Denotes newly listed study