ACTIVE CANCER CLINICAL TRIALS  
February 2016

Clinical Trials Nurses
Joanie 330-489-1274  
Jane 330-588-4589  
Tara 330-588-4588

Changed
• S1406 – Re-opened
• OncoCyte PRO068 – Changed from “Suspected or newly dx NSCLC with smoking hx” to “Ongoing management for lung nodule or newly dx NSCLC with smoking hx”

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

Suspended ...Phase II
Subprotocol A: Afatinib in (Other Than Small Cell and NSCLC) Mutations of EGFR

Subprotocol B: Afatinib in HER2 Activating Mutations

Subprotocol E: AZD9291 in EGFR T790M Mutations (Except NSCLC) or Rare Activating Mutations of EGFR

Subprotocol F: Crizotinib in (Other Than Adenocarcinoma of Lung or ALCL) with ALK Rearrangements

Subprotocol G: Crizotinib in ROS1 Translocations (Other Than NSCLC)

Subprotocol H: Dabrafenib and Trametinib in BRAF V600E or V600K Mutations (Excluding Melanoma and Thyroid Cancer)

Subprotocol Q: Ado-trastuzumab Emtansine in HER2 Amplification (Except Breast and Gastric/Gastro-Esophageal Junction (GEJ) Adenocarcinomas)

Subprotocol R: Trametinib in BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations

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)

BRAIN METS

Brain mets outside a 5mm margin around hippocampus

Pending 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

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

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 lapanib

COLORECTAL

Any stage newly dx colorectal adenocarcinoma with dx in 2013-2016 ............................................................... OSU OCCPI

Tissue submission for MSI + IHC +/- methylation – screening for Lynch Syndrome

Unresectable, metastatic or locally advanced, colorectal adenocarcinoma, 2nd or 3rd line .................................... SWOG S1406

Step 1: BRAF V600E testing (provided by trial if not already done) – must be positive to continue

Step 2: cetuximab + irinotecan vs vemurafenib + cetuximab + irinotecan

at progression, optional

vemurafenib + cetuximab + irinotecan

Metastatic/advanced CRC, K-ras wild-type, after first-line tx with oxaliplatin-containing chemo and bevacizumab .ECOG E7208

Phase II IRB review pending – 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  150mg/m²  400mg/m²  6mg/kg
**RECTAL**

Locally-advanced rectal

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

- **Group 1:** FOLFOX q 2 wks x 6 (without radiation)
  - If regression $\geq 20\%$ 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)

- **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.

**OVARIAN, PERITONEAL or FALLOPION TUBE**

Recurrent or persistent epithelial ovarian, primary peritoneal or fallopian tube cancer,

**mucinous histology not eligible** .................................................................NRG-GY003

**Pending PI protocol-specific training**

<table>
<thead>
<tr>
<th>Nivolumab (3mg/kg)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>q2wksx4</td>
<td>q2wks for max 42 doses</td>
<td>q3wksx4</td>
<td>q2wks for max 42 doses</td>
</tr>
</tbody>
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<tr>
<th>Nivolumab + Ipilimumab (3mg/kg)</th>
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</table>

**PROSTATE**

***Castration resistant metastatic prostate ..................................................Alliance A031201

**Pending PI protocol-specific training**

<table>
<thead>
<tr>
<th>Enzalutamide (160mg daily)</th>
<th>Enzalutamide (160mg daily)</th>
<th>+ Abiraterone (1000mg daily)</th>
<th>+ Prednisone (5mg 2x daily)</th>
</tr>
</thead>
</table>

**HEAD AND NECK**

Locally-advanced resected head and neck cancer -- *Gross total resection of tumor; no prior chemo* ......................... RTOG 0920

- **T1, N1-2 or T2-4a, N0-2, M0**
  - RT (2 Gy/day, in 30 fractions for total of 60 Gy)
  - vs
  - Cetuximab then RT (as above) + Cetuximab then Cetuximab

<table>
<thead>
<tr>
<th>Cetuximab initial dose 400 mg/m$^2$</th>
<th>250 mg/m$^2$/week x 6</th>
<th>250 mg/m$^2$/week x 4</th>
</tr>
</thead>
</table>

**MDS**

Low- or Intermediate-1 Risk MDS and Symptomatic Anemia .................................................................ECOG E2905

**Pending lenalidomide counselor training**

- Del 5q31.1:  
  - Arm A -- Lenalidomide until relapse/progression/no MER then cross over to Arm B
  - Not Del 5q31.1:  
    - Arm A -- Lenalidomide until relapse/progression/no MER then cross over to Arm B
    - or
    - Arm B -- Lenalidomide + epoetin alfa until relapse/progression

**LYMPHOMA**

Untreated early-stage diffuse large B-cell lymphoma ................................................................. SWOG S1001

- R-CHOP then
- PET negative - R-CHOP x 1 or PET positive - IFRT then Zevalin

**Newly Dx diffuse large B-cell lymphoma, Phase II** .................................................................ECOG E1412

**Pending lenalidomide counselor training**

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| Lenalidomide + R-CHOP vs RCHOP |
|------------------------------|----------------------------|

*** Denotes newly listed study
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

\[
\begin{align*}
&1mg/kg & 3mg/kg & 250ug sq \\
&d1 & d1 & d1-14
\end{align*}
\]

then maintenance up to 2 yrs:

Nivolumab + Sargramostim

\[
\begin{align*}
&3mg/kg & 250ug sq \\
&d1 & d1-14
\end{align*}
\]

MULTIPLE MYELOMA

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

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

Pending lenalidomide counselor training

FISH testing must be done ≤ 90 days prior to registration

Induction:

Bortezomib + Lenalidomide + Dexamethasone (q 3wks x 12) vs Carfilzomib + Lenalidomide + Dexamethasone (q 4wks x 9)

\[
\begin{align*}
&1.3mg/m^2 SQ or IV & 25mg PO & PO \\
&15mg PO & 20mg/m^2 IV cycle 1 & 25mg PO & PO & 36mg/m^2 IV cycle s 2-9
\end{align*}
\]

then

Maintenance:

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

\[
\begin{align*}
&15mg PO & 15mg PO
\end{align*}
\]

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

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

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)

Unresectable Stage IIIA/B non-squamous NSCLC – Phase II ..................................................................................... NRG 1306

IRB review pending -- Can be expedited upon request

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

** Denotes newly listed study
Unresectable Stage IIIA/B NSCLC – Phase II

Pending RT credentialing

**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

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SQUAMOUS NSCLC

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

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:**

- **PI3K:** GDC-0032 (4mg daily)
- **CDK4/6:** Palbociclib (125mg daily [3 wks on / 1 wk off])
- **FGFR:** AZD4547 (80mg BID daily)

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Unresectable Stage IIIA/B NSCLC – Phase II

Pending RT credentialing

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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