

BRAIN

RTOG 0627
RTOG 0614

Phase II Recurrent GBM: Dasatinib
WBRT: Memantine/Placebo for prevention of cognitive dysfunction with WBRT

BREAST

Neoadjuvant
NSABP B-40*

Her2 neg / 2 cm palp & operable invasive, s/p core biopsies: 4 add'l cores* → Docetaxel +/- Capecitabine or +/- Gemcitabine → A/C +/- Bevacizumab → surgery +/- Bevacizumab x 10

NSABP B-41

Her2 Pos / 2cm palp & operable, s/p core bx: AC→T + 1) Herceptin or 2) + Lapatinib or 3) + Herceptin & Lapatinib

BREAST

Adjuvant
RTOG 0413*

Stage 0, I, II tumor ≤ 3 cm, ≤ 3 + nodes s/p lumpectomy: WBI vs PBI (Now enrolling high-risk pts only)
ER &/or PR + Node – Breast Cancer: Oncotype DX Assay followed by treatment stratification
HER2 (-), LN(+) or high risk LN (-); Doxorubicin & Cyclophosphamide followed by Paclitaxel +/- Bevacizumab

TAILORx

ECOG 5103

Metastatic

Duke's BCWG 01

triple negative Stage IV or inoperable stage III: Abraxane weekly + Carboplatin weekly + Bevacizumab in 1st & 2nd line metastatic

Duke's BCWG 02
Duke's BCWG 03

Inoperable Stage III or IV; Dasatinib po
Brain metastasis after definitive WBI: Bevacizumab + single-agent chemo

SWOG S0622
RTOG 0517

Bone Mets predominant: Dasatinib po 100mg vs 140mg
Bone Mets Asymptomatic/Stable low pain scale (Lung, Breast, Prostate): Zometa + Ca/Vit D +/- Radiopharm
Bone Mets using Zoledronic Acid: observational study of ONJ

S0702

CALGB 40502

1st line locally adv/met: Bevacizumab + Paclitaxel or Ixabepilone or Nab-Pacitaxel

ACORN

1st or 2nd line locally adv / met: Gemcitabine or Capecitabine + Sorafenib/placebo (must have had Bev previously, may have had Cap or Gem prior)

CTSU N0733

Stage IIIB or IV, ≤2 prior tx including anthracycline and/or taxane: Capecitabine + Lapatinib +/- IMC-A12 – **Temp susp 4/19/09**

AVF4349n (VIRGO)

Registry: Locally Adv or Met BC 1st line tx with chemo or target therapy for HER2 normal or hormone therapy for HER2 +

GASTROINTESTINAL

Anal

No studies available at this time

Rectal

NSABP R-04

Neo-adj stage II or III & resectable Rectal:
CI 5FU+RT vs. CI5FU+Oxali+RT vs. Xeloda+RT vs. Xeloda+Oxali+RT (Pre-study research biopsy optional)

Colorectal

CALGB 80405

Untreated MCRC: FOLFIRI or FOLFOX + Avastin or Erbtux or Avastin & Erbtux
2nd line MCRC after failing oxaliplatin (+/- Avastin) regimen: FOLFIRI + Aflibercept or Placebo

Colon

ECOG 5202

HR Stage II Colon Cancer: 5FU/LCV/Oxal vs 5FU/LCV/Oxal/Bevacizumab – temp susp for consent updates (expected to open Oct)

Esophageal

Xelox-A (Duke)

1st line inoperable metastatic or locally adv adeno carcinoma esophagus or stomach:
Bev/Capecitabine/Oxal.

RTOG 0436 *

non-surgical, 1st line: RT + Paclitaxel + Cisplatin +/- Cetuximab

Gallbladder/Cholangiocarcinoma

No studies available at this time

Gastric

Xelox-A (Duke)

1st line inoperable metastatic or locally adv adeno carcinoma esophagus or stomach:
Bev/Capecitabine/Oxal.

SWOG S0502

Met or unresectable GIST: Imatinib +/- Bevacizumab (any line, but no previous therapy with Imatinib/Bev/or similar targeting agents)

GENITOURINARY

Prostate

CALGB 90203

Neo-Adjuvant High-risk, localized: Docetaxel + AD → Radical Prostatectomy vs Immediate Radical Prostatectomy (Imbedded optional QOL)

RTOG 0621*

Adjuvant high risk: 3DCRT/IMRT + Androgen Suppression and Docetaxel**

ECOG 3805

RTOG 0517

Metastatic Ds: Androgen Deprivation +/- Docetaxel
Bone Mets Asymptomatic/Stable low pain scale (Lung, Breast, Prostate): Zometa + Ca/Vit D +/- Radiopharm

SWOG S0421

Advanced Hormone Refractory: Docetaxel +/- Atresentan

CCCWFU 97405

Prostate Cancer with Hot Flashes: soy protein or Effexor or soy protein & Effexor or placebo.

Renal

ECOG E2805

Resected pT1b-T4 Renal Cell: Sunitinib vs Sorafenib vs Placebo (Optional sample companion E1Y03) **PRE-OP pre-registration preferred** but post-op allowed-
Metastatic, 1st or 2nd line: Bevacizumab alone OR Bevacizumab + Sorafenib or Temsirolimus OR Sorafenib & Temsirolimus (no Bev)

ECOG E2804

Urothelial

RTOG 0524

Muscle Invasive Bladder Cancer for Non-Cystectomy candidates: Taxol/Herceptin/RT vs Taxol/RT (**temp susp 6/08/09 – expect to open Oct**)

HEAD & NECK

ECOG E1305

recurrent/met: cisplatin doublet +/- Bevacizumab

LYMPHOMA

Hodgkin's

CALGB 50602

relapse/refractory: Galiximab – **temp susp (1/26 interim analysis)**
refractory/recurrent <30yo: Bortezomib + Ifosfamide/vinorelbine **temp susp 4/09**

COG AHOD0521

Non-Hodgkin's

CALGB 10002

Untreated Burkitt Lymphoma/Leukemia: Rituxan + High Intensity Chemo + G-CSF – (Mand. Comp 8461, 9665, 9764-**MARROW NEEDED**)

CALGB 50501

Mantle Cell: Velcade + Lenalidomide

LUNG

NSCLC

ACoSOG Z4032

High Risk NSCLC ≤ 3 cm: Sublobar Resection vs. Sublobar Resection + Brachytherapy

SWOG S0424

SWOG S0533

NSCLC– Epidem. Case Series Non-Smokers Only
Inoperable Loc. Adv Stage III – Cispatin/Etoposide +/- Bevacizumab **Low Risk Only**

RTOG 0617*

Stg IIIA/B: high vs low dose RT with concurrent Consolidation Carboplatin/Paclitaxel +/- Cetuximab
unresectable stg IIIA or IIIB: Abraxane + Carboplatin 8wks followed by XRT + Erlotinib
2nd line: Erlotinib vs Pemetrexed - tissue required for EGFR analysis

CALGB 30605

CTSU N0723

CALGB 30704

RTOG 0517

ACRIN 6678*

SWOG 0709

2nd line Stg IIIB or IV: Pemetrexed or Sunitinib or Pemetrexed & Sunitinib
Bone Mets Asymptomatic/Stable low pain scale (Lung, Breast, Prostate): Zometa + Ca/Vit D +/- Radiopharm
Stg IIIB w/ pleural effusion or IV: FDG PET as an response indicator for pts receiving a platinum doublet with or without Bev or Cetuximab (physician choice) – **Protocol scans required prior to tx**
Stg IIIB/IV with PS=2, 1st line: Erlotinib alone vs Carbo/Platinum/Paclitaxel + Erlotinib. **Serum required for proteomics prior to enrollment**

Adjuvant

CTSU E1505

Resected Stg IB-IIIa: Chemo (3 Cisplat options) +/- Bevacizumab
Resected/MAGE A3 positive: MAGE A3 ASCI or placebo alone or after 4 cycles of chemo
Resected IB-IIIa: Tx assigned by tumor genomics, Vinorelbine/Cisplatin or Pemetrexed/Cisplatin (**Fresh Tissue Required**)

GSK 109403 (Magrit)

TOP0703

SCLC

CALGB 30610

M06-822

limited stage: Cisplatin/Etoposide + RT 45Gy BID vs. 70Gy daily vs. 61.2G concomitant boost
1st line for extensive ds or progressive or refractory: ABT-263

Mesothelioma

SWOG 0722

Unresectable, 2nd or 3rd line after platinum based therapy : Everolimus

LEUKEMIA – Marrow required for ALL leukemia studies

COG AAML0531

AML < 30 years, Newly Dx: Conventional Chemotherapy +/- Mylotarg (includes SCT for HR)
AML Untreated >60yo: Hydroxyurea + Azacitidine + Gemtuzumab → Azacitidine + Gemtuzumab → Azacitidine

SWOG S0703

CALGB 10002

COG AALL0232

COG AALL0433

COG AALL0434

Burkitt Lymphoma/Leukemia, Untreated: Rituxan + High Intensity Chemo + G-CSF – (Mand. Comp 8461, 9665, 9764-**MARROW NEEDED**)
High risk B-precursor ALL <31yo: (Dex or Pred) + (MTX or HD MTX)
Int. Risk relapse B-precursor ALL <29.99yo: std vs. intensive VCR
Newly dx T-cell ALL <31yo: MTX, Nelarabine, aug. BFM

MELANOMA

ECOG 1697

SWOG S0438

T2-4,N0 or T1-4,N1a-2a: obs vs. 4wks high dose INF-α2b
Metastatic: Sorafenib/Temsirolimus or Sorafenib/Tipifarnib. – **temp susp (int analysis 2/15)**

MULTIPLE MYELOMA (Jav)

CTSU EIA06

CTSU EIA05

SWOG S0777

newly dx, not high-dose candidate: Melphalan + Prednisone + either Thalidomide or Revlimid completed Dexa-based induction: Velcade / Revlimid / Dexamethasone vs. Velcade / Dexamethasone newly dx without intent for immediate transplant: Lenalidomide/Dexa vs. Lenalidomide/Dexa/Bortezomib

MDS

Duke Cephalon

Duke Sorafenib

denovo or secondary any line: Decitabine, Arsenic Trioxide, and Ascorbic Acid
MDS or CMML any line: Sorafenib

PANCREAS

ACoSOG Z5041

Operative Adeno: Gemcitabine + Erlotinib → sugery → Gemcitabine + Erlotinib

SARCOMA

COG studies available for: Ewing's with Pulmonary Mets (<50yo), low risk rhabdo (<50yo), & int risk rhabdo (<50yo)

OTHER

RTOG 0517

Bone Mets Asymptomatic/Stable low pain scale (Lung, Breast, Prostate): Zometa + Ca/Vit D +/- Radiopharm

URCC 07004

Chemotherapy Peripheral Neuropathy: topical Amitriptyline & Ketamine vs. placebo