

## Hematologic

Mel (86519, #5910) / Liz (88260, #0120)

### Malignant Heme

#### Leukemia/Lymphoma

**IRB #H-37452/ LCCC #1637:** Brentuximab Vedotin w/ Cyclophosphamide, Doxorubicin, Etoposide, & Prednisone (BV-CHEP) for Adult T-Cell Leukemia/ Lymphoma: A Ph II Trial - *Sloan*

**IRB # H-38532/ AMC #101:** Pilot Study of Ibrutinib & R-da-EPOCH for Front Line Tx of AIDS-Related Lymphomas – *Sloan; Mel / Anthony A (45729, #0402)*

**CIRB #H-39514/ SWOG #S1826:** Ph III, Rand. Study of Nivo + AVD or Brentuximab Vedotin + AVD in Newly Dx Advanced Stage Classical Hodgkin Lymphoma - *Sloan*

**IRB #H-39342/ DFCI #18-089:** Ph I/II Study of Duvelisib & Venetoclax in Relapsed/Refractory CLL, SLL, or Richter's Syndrome - *Sloan*

#### Multiple Myeloma:

**CIRB #H-39488/ SWOG S1803 (DRAMMATIC):** Ph III Study of Daratumumab + Lenalidomide or Lenalidomide as Post-A SCT Maintenance in MM Using MRD to Direct Tx Duration - *Santhorawala*

**WIRB #H-40731/ AbbVie #M13-494:** Ph 3, Rand. Study of Venetoclax + Dex v Pom + Dex in t(11;14)+ Relapsed/Refractory MM - *Edwards*

**IRB #H-39242/ DFCI #19-291 IxaPomDex:** Ph I/II Study of Twice Weekly Ixazomib + Pomalidomide + Dexamethasone in Relapsed or Refractory MM – *Santhorawala*

### Benign Heme

#### Primary Immune Thrombocytopenia:

**Advarra IRB #H-41733/ Takeda #TAK-079:** Ph 2, Rand., Dbl-Blnd, Placebo-Ctrl Study to Eval. Safety, Tolerability, & Efficacy of TAK-079 in Persistent/Chronic ITP - *Sloan (pending Advarra IRB approval)*

## Sickle Cell

Mel (86519, #5910) / Anthony A (45729, #0402)

**IRB #H-35777/ UPMC #PRO15110016 (STERIO-SCD):** A Ph II Rand, Dbl-Blnd, Placebo-Controlled Study to Assess the Safety, Tolerability, & Efficacy of Riociguat in Pts w/ Sickle Cell Diseases - *Klings*

**IRB #H-36459/ BMT CTN #1503 (STRIDE-2):** A Study to Compare Bone Marrow Transplantation to Standard Care in Adolescents & Young Adults w/ Severe Sickle Cell Disease - *McMahon*

**Central IRB #H-39846/ NHLB #SCD-CARRE:** Sickle Cell Disease & Cardio-vAscular Risk - Red cell Exchange Trial - *Klings*

**Advarra IRB #H-40856/ Forma #4202-HEM-301 (HIBISCUS):** Adaptive, Rand., Placebo-Ctrl, Dbl-blnd, Study of Oral FT-4202, a Pyruvate Kinase Agonist in Pts w/ Sickle Cell Disease - *Klings*

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## Links

NCI Cancer Trials Support Unit: [CTSU.org](http://www.ctsu.org)

SWOG Oncology: [SWOG.org](http://www.swog.org)

NRG Oncology: <http://www.nrgoncology.org>

AIDS Malignancy Consortium: [pub.emmes.com/study/amc](http://pub.emmes.com/study/amc)

Amyloid Center: <http://www.bu.edu/amylloid/>



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## Cancer & Hematology Clinical Research Program



Active Clinical Trials

September 2021

<http://www.bumc.bu.edu/clinicaltrials>

650 Albany St, EBRC-4  
Boston, MA 02118  
(617) 638-8265



## Breast

Alex (87513, #5912) / Liz (88260, #0120)

**CIRB #H-37507 CTSU #A011202:** A Rand. Ph III Trial of ALND v Axillary RT in Breast Ca Pts w/ (+) Sentinel LN Dz After NAC - Cassidy

**IRB #H-39510/ DFCI #17-101 (PACE):** Palbociclib After CDK & Endocrine Tx (PACE): A Rand. Ph II Study of Fulvestrant, Palbociclib, & Avelumab for Endocrine Pre-tx ER+/HER2- Met, Breast Ca - Ko

**CIRB #H-40381 CTSU #EA1181 (CompassHER2-pCR):** Preop THP & Postop HP in Pts w/ Path. CR - Ko (pending)

## Cutaneous

Mel (86519, #5910) / Liz (88260, #0120)

### Melanoma:

**CIRB #H-38640/ SWOG #S1801:** Ph II Rand. Study of Adjuvant vs Neoadjuvant Pembro for Clinically Detectable St III-IV Melanoma - Lerner

**CIRB #H-41279/ CTSU #EA6192 (PET-Stop):** Ph II Study of Biomarker Driven Early D/c of Anti-PD-1 Therapy in Advanced Melanoma - Lerner (pending)

## Gastrointestinal

Alex (87513, #5912) / Annie (88213, #0511)

### Colorectal:

**CIRB #H-37277/ CTSU #A021502:** Rand. trial of standard chemo +/- Atezolizumab as adjuvant tx for dMMR St III colon cancer - Addo-Tabiri

**CIRB #H-39558/ CTSU #A021703 (SOLARIS):** Rand. Dbl-Blnd Ph III Trial of Vitamin D3 in Untreated Metastatic Colorectal Ca - Addo-Tabiri

**WIRB #H-40781/ G1 Therapeutics #G1T28-207 (PRESERVE1):** Ph 3 Rand, Dble-blnd Trial of Trilaciclib v Placebo in Pts Receiving FOLFOXIRI/Bev for Metastatic Colorectal Ca - Kulke

### Neuroendocrine:

**CIRB #H-38045/ CTSU #A021602 (CABINET):** Rand. Dbl-Blnd Ph III Study of Cabozantinib vs Placebo in Advanced Neuroendocrine Tumors after Progression on Prior Therapy - Kulke

**NEIRB #H-40767/ ITM #LET (COMPETE):** Rand. Ph III Study of PRRT w/ 177Lu-Edotreotide vs Everolimus in Inoperable, Progressive, SSTR+, GEP-NETs - Kulke (pending)

**WCG IRB #H-41709/ DFCI #19-403:** Ph II trial of cabozantinib + nivolumab for advanced carcinoid tumors - Kulke (pending)

### Hepatobiliary:

**HIRB #2019-51/ Merck #KEYNOTE 937:** Ph 3 Dble-blnd Study of Pembro v Placebo as Adjuvant Tx in Pts w/ HCC & Complete Radiological Response after Surgical Resection or Ablation - Marks

**IRB #H-42011 / HCRN #G110-405:** Rand. Ph III Study of Atezo + Bev w/ Y-90 Unresectable HCC - Kulke (not yet submitted to IRB)

### Anal:

**CIRB #H-39855/ CTSU #EA2182 (DECREASE):** A Rand. Ph II Study of De-Intensified ChemoXRT for Early-Stage Anal SCC - Mak

### Pancreatic:

**CIRB #H-40808/ CTSU #A021806:** A Ph III Trial of Peri-op vs Adjuvant Chemo for Resectable Pancreatic Cancer - Sachs

## Genitourinary

Anthony S (85612, #6631) / Liz (88260, #0120)

### Prostate:

**IRB #H-29665/ BMC #Prostate CK:** Feasibility/Outcomes Study of Hypofractionated SBRT as a Boost to the Prostate for Localized, High Risk Prostate Cancer - Hirsch

**CIRB #H-37226/ NRG #GU005:** Ph III IGRT & SBRT vs IGRT & Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer - Hirsch

## Head & Neck

Mel (86519, #5910) / Annie (88213, #0511)

### Head & Neck SCC:

**CIRB #H-32379/ RTOG #R1216:** Rand. Ph II/III Trial of Adjuvant RT w/ Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in High-Risk SCC of the H&N - Truong

**WIRB #H-39961/ Celgene #VTX-2337:** Ph 1b Pre-Op Study to Evaluate Biomarker Modulation in Response to Motolimod + Nivo in Resectable SCC of the H&N - Faden

**CIRB #H-37278/ NRG #HN004:** Rand. Ph II/III Trial of RT + Concurrent Durva vs. RT + Concurrent Cetuximab in Locoregionally Advanced H&N Cancer w/ Contraindication to Cisplatin - Truong (temp closure)

**IRB #H-38134/ RTOG Foundation #R3507:** A Rand. Ph II study of Pembro + SBRT Re-Irradiation v SBRT Alone for Locoregionally Recurrent or 2nd Primary H&N Ca - Truong

**CIRB #H-39827/ NRG #HN005:** Rand. Ph II/III Trial of De-Intensified RT for Early-Stage, p16+, Non-Smoking Assoc. Oropharyngeal Cancer - Truong (pending)

**CIRB #H-41338/ NRG #HN006:** Rand. Ph II/III Trial of Sentinel Lymph Node Biopsy v Elective Neck Dissection for Early-Stage Oral Cavity Cancer - Truong (pending CIRB approval)

### Nasopharyngeal:

**CIRB #H-33148/ NRG #HN001:** Rand. Ph II & III Studies of Tx for Nasopharyngeal Ca Based on Epstein Barr Virus (EBV) DNA - Truong

## Lung

Anthony S (85612, #6631) / Annie (88213) / Sarah (87559, #8956)  
NSCLC:

**CIRB #H-33418/ CTSU #A151216 (ALCHEMIST):** Adjuvant Lung Cancer Enrichment Marker Identification & Sequencing Trial - Everett

**CIRB #H-40717/ CTSU #A081801 (ACCIO):** Integration of Immunotherapy into Adjuvant Tx for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO) - Tapan

**CIRB #H-33425/ CTSU #E4512:** A Ph III Trial for Resected Early Stage NSCLC: Crizotinib v Obs. for Pts w/ Tumors ALK+ - Everett

**CIRB #H-36723/ NRG #LU002:** Maintenance Systemic Tx vs Local Consolidative Tx (LCT) + Maintenance Systemic Tx for Limited Met. NSCLC: Rand. Ph II/III Trial - Mak

**WIRB #H-40344/ DFCI #19-523:** Pilot study of serial plasma genotyping to guide tx of advanced NSCLC receiving 1st-line pembro - Tapan

**CIRB #H-40842/ CTSU #EA5181:** Rand. Ph III Trial of Durvalumab as Concurrent + Consolidative Tx or Consolidative Tx Alone for Unresectable St 3 NSCLC - Tapan

**Cop. IRB #H-40633/ EMD Serono #MS-0031 (INSIGHT 2):** Ph II, Study of Tepotinib + Osimertinib in MET Amplified Advanced/Met. NSCLC w/ EGFR Mutations & Acquired Resistance to Prior Osimertinib - Tapan

**WIRB #H-40642/ Janssen #NSC1001:** Ph 1/1b Study to Evaluate Safety & PKs of JNJ-73841937 (Lazertinib), alone or w/ JNJ-61186372, an EGFR & cMet Antibody in Advanced NSCLC - Tapan

### SCLC:

**CIRB #H-40325/ SWOG S1827 (MAVERCK):** MRI Brain Surveillance Alone vs MRI Surveillance + PCI: A Rand. Ph III Trial in SCLC - Mak

**CIRB #H-41197/ NRG #LU007 (RAPTOR):** Rand. Ph II/III Trial of Consolidation RT + IO for ES-SCLC: RAPTOR trial - Mak (pending)

### Esophageal:

**CIRB #pend/ CTSU #EA2174:** Ph II/III Study of Peri-op Nivo + Ipi in Locoregional Esophageal & GEJ Adeno - Assi (not yet submitted to IRB)

## Amyloidosis

Mel (86519, #5910) / Liz (88260, #0120)

**IRB #H-35835/ BMC #Evomela:** A Ph II Open-Label, Safety & Efficacy Study of Propylene Glycol-Free Melfalan Hydrochloride (Evomela) in AL Amyloidosis Pts Undergoing ASCT - Sloan; Faniela (88247, #0045) / Sarah (87559, #8956)

**Advarra IRB #H-36982/ Oncopeptides AB #OP201:** An Open-Label, Ph 1/2 Study of Melflufen & Dexamethasone for Pts w/ AL Amyloidosis Following at Least One Prior Line of Tx - Sanchorawala (temp closure)

**WIRB #H-39485/ Caelum Bio #CAEL-101 301:** Ph 3, Dbl-Blnd, Study of CAEL-101 + Plasma Cell Dyscrasia Tx (PCDT) vs Placebo + PCDT in Tx-Naive Pts w/ Mayo Stage IIIb AL Amyloidosis - Sanchorawala

**WIRB #H-40375/ Caelum Bio #CAEL-101 302:** Ph 3, Dbl-Blnd, Study of CAEL-101 + Plasma Cell Dyscrasia Tx (PCDT) vs Placebo + PCDT in Tx-Naive Pts w/ Mayo Stage IIIa AL Amyloidosis - Sanchorawala

**IRB #H-39705/ Cornell Janssen DPd:** Daratumumab, Pomalidomide & Dex (DPd) in Relapsed/Refractory AL Amyloidosis Pts Previously Exposed to Dara - Sanchorawala

**WIRB #H-40919/ Sorrento #STI-6129:** Ph 1, Dose-Escalation Safety & Efficacy Study of STI-6129 in Relapsed/Refractory Systemic AL Amyloidosis - Sanchorawala

**Advarra IRB #H-41609/ Prothena #NEOD001-301:** Ph 3, Rand., Dble-Blnd, Efficacy & Safety Study of Birtamimab + SOC Care vs. Placebo + SOC in Mayo Stage IV AL Amyloidosis - Sanchorawala (pending)