

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-ASCT Maintenance in MM Using MRD to Direct Tx Duration - Sanchorawala

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 - Sanchorawala

Sickle Cell

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

IRB #H-35777/ UPMC #PRO15110016 (STERIO-SCD): A Ph II Rand, Dbl-Blind, 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

WIRB #H-39245/ Novartis #SEG101 (STAND): A Ph III, Rand., Dble-blind Study to Assess 2 Doses of Crizanlizumab vs placebo, +/- Hydroxyurea/ Hydroxycarbamide Tx, in Adolescent & Adult Sickle Cell Disease Pts w/ Vaso-Occlusive Crises (STAND) - Klings

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

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

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Links

Cancer Trials Support Unit: CTSU.org

SWOG Oncology: SWOG.org

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

AIDS Malignancy Consortium: pub.emmes.com/study/amc

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



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Breast

Anthony S (85612, #6631) / **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 CIRB approval**)

Cutaneous

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

Melanoma:

CIRB #H-38640/ SWOG #S1801: A 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 Discontinuation of Anti-PD-1 Therapy in Advanced Melanoma (PET-Stop) – *Lerner* (**pending**)

Gastrointestinal

Anthony S (85612, #6631) / **Charlie** (88274, #8956)

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*

Anal:

CIRB #H-38309/ CTSU #EA2165: A Rand. Ph II Study of Nivo after Combined Modality Tx (CMT) in High Risk Anal Cancer – *Addo-Tabiri*

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

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**)

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 - *Kulke*

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) / **Charlie** (88274, #8956)

Head & Neck SCC:

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

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*

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 IRB 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) / **Charlie** (88274, #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) - *Tapán*

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 - *Tapán*

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

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 - *Tapán*

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 - *Tapán*

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 - *TBD* (**not yet submitted to IRB**)

Amyloidosis

Mel (86519, #5910) / **Hannah** (88434, #0483)

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*

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*

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-Naïve Pts w/ Mayo Stage IIb 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-Naïve 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 or Refractory Systemic AL Amyloidosis - *Sanchorawala*

Advarra IRB #H-41609/ Prothena #NEOD001-301: Ph 3, Rand., Dble-Blnd, Efficacy and Safety Study of Birtamimab + Standard of Care vs. Placebo + Standard of Care in Mayo Stage IV AL Amyloidosis - *Sanchorawala* (**not yet submitted to IRB**)

Hematologic Malignancies

Mel (86519, #5910) / **Hannah** (88434, #0483)

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*