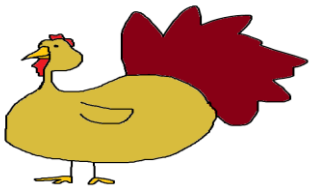
Holy Cross Hospital
Michael and Dianne Bienes Comprehensive Cancer Center

Oncology Clinical Trial List
November 2018



Solid Tumors and SCCHN

Dose escalation: *Advanced solid tumors or metastasis (incl. lymphoma) located in the head, neck or thoracic region* ***amenable to palliative radiation****, SCCHN 1L with curative intent* ***and cPOP (skin lesions). cPOP-naïve, any indication for high dose palliative RT.***	An Open Label, Phase Ia/Ib Trial of the DNA-PK Inhibitor MSC2490484A in Combination with Radiotherapy in Patients with Advanced Solid Tumors. **EMR 100036-002 PI - Segota (CRA - Eileen)**
Failed standard therapy	A Phase Ib Open-Label, Dose-Finding Trial to Evaluate the Safety, Tolerability, and Pharmacokinetics of Avelumab in Combination with M9241 (NHS-IL12) in Subjects with Locally Advanced, Unresectable, or Metastatic Solid Tumors **EMD Serono MS201781-0031 PI - Segota (CRA - TBA)** SIV 12/5/18

Precision Medicine Basket Trials

Screening: Large 1B; IIA or IIB; NSCLC/Squamous Stage IB – IIIA; free testing for EGFR, ALK and PD-L1	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) **ALLIANCE A151216 (Any CRA)**
After all approved treatments with overall survival have been exhausted *See page 4 for for list of mutations* *	Molecular Analysis for Therapy Choice (NCI - MATCH) **ECOG-ACRIN EAY131 (mutations on page 4) (Any CRA)**
Currently enrolling in 4 cohorts: *1.NSCLC with RET fusions, except for KIF5B-RET* *2.Any advanced solid tumor type with Loss of function mutation in CBL.* *3.Any advanced solid tumor type with Chr4q12 amplification (KDR/KIT/PDGFRA). (Prefer 2 of these 3 genes amplified)* *4.Any advanced solid tumor type with activating mutations, fusions or amplification of AXL* *MGCD516 - tyrone kinase inhibitor* *Mut/Amp/Rearrange: RET; KDR; PDGFRA; KIT; NTRK; DDR2; MET, SAXL or CBL Loss* *Phase 1b to receive* *Must test positive for target molecular tumor marker, with or without previous tumor profiling identified.* *Unresectable or metastatic disease for which standard treatment is not available.* *If no tissue available, molecular testing will be available for NSCLC, melanoma, and non-GIST sarcoma patients*	A Phase 1/1b Study of MGCD516 in Patients With Advanced Solid Tumor Malignancies [unresectable or metastatic] **Mirati 516-001 PI - Azzi (CRA - Kathy)**

Breast

Triple negative - - First line-HRD+ or BRCA+, No HRD needed. Chemo + Nivo followed by Nivo/Placebo + Rucaparib/Placebo	A phase 3, Randomized, Double Blinded, placebo-controlled study of nivolumab in combination with chemotherapy followed by maintenance therapy with nivolumab in combination with rucaparib, nivolumab monotherapy or rucaparib monotherapy versus chemotherapy for previously untreated locally recurrent unresectable or metastatic triple negative breast cancer. **BMS CA209-8ER PI - Segota (Eileen/TBA)** Sponsor pending until 2019

Breast (Cont'd)

HER-2 negative *High risk node negative, stage II/III within 1 year of diagnosis*	A Randomized Phase III Double-Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial **Alliance A011502 (CRA - Any CRA)**
*Histologically confirmed solid tumors that are refractory and **intolerant or ineligible for standard therapy*** *(In this phase, only triple negative breast)*	A Multi-Center Dose Finding, Open Label, Phase 1 Study of RX-5902 in Subjects with Advanced or Metastatic Solid Tumors **Rexahn RX-5902-P1-01 - PI Segota (Sheryl/Eileen)** Open to Accrual
*Pre/Post menopausal, ER Positive HER 2 negative metastatic BC progressed on **recent line of**; 2 hormonals, one prior hormonal/Chemotherapy or one hormonal+ a CDK4/6 inhibitor*	A Phase I-II multicenter, open label trial of H3B-6545, a covalent antagonist of estrogen receptor alpha, in women with locally advanced or metastatic estrogen receptor-positive, HER2 negative breast cancer **H3 Biomedicine Inc. H3B-6545-A001-101 PI - Seigel (CRA - TBA)** SIV 11/9/18
*Histologically confirmed unilateral primary invasive breast adenocarcinoma w/in 18 months *Positive for ER and/or PgR *Patient has HER2-negative breast cancer *Surgical resection - anatomic stage group II or III	A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer (New Adjuvant TriAL with Ribociclib [LEE011]: **NATALEE**) **Novartis CLEE011O12301C (TRIO033)** Approved as site

CALLER Registry: Collaborative Attempt to Lower Lumpectomy Re-excision Rates PI - Casey

Non-small Cell Lung Cancer

MET *Met amplification* *Exon14 skipping alterations* *Provides Oncomine Focus Assay or Guardant Liquid Biopsy Report; 1st or 2nd line of treatment*	A Phase II single-arm trial to investigate tepotinib in advanced (Stage IIIB/IV) non-small cell lung cancer with MET exon 14 (METex14) skipping alterations (VISION) **cMet MS200095-022 PI - Drew (CRA - Kathy or Sheryl)**
Stage IIIB or IV NSCLC at time of Guardant blood collection. Or patients with initial diagnosis of Stage I-IIIa NSCLC now recurrent or metastatic Stage IIIB or IV. No prior systemic therapy; OR meet all 3 conditions: 1) history of prior systemic therapy 2) disease progression w/in past four weeks 3) No new systemic therapy	GEODE: Registry of Guardant360® Use and Outcomes In People With Advanced Cancer **Guardant Health 01-MX-003 (GEODE) PI - Azzi (CRA - Sheryl)**
Erlotinib *EGFR* *If EGFR detected on Alchemist screening*	Randomized Study of Erlotinib vs Observation in patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC) **Alliance A081105 (Alchemist EGFR) (Any CRA)**
Crizotinib *ALK Fusion Protein* *If ALK detected on Alchemist screening*	A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein **ECOG-ACRIN E4512 (Alchemist ALK) (Any CRA)**
Adjuvant Nivolumab *If no ALK/EGFR detected on Alchemist screening*	Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) – A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers **ECOG-ACRIN EA5142 (Alchemist immuno) (Any CRA)**

Non-small Cell Lung Cancer (Cont'd)	
MET Amplification or mutation Novartis Rapid start-up trial; platinum doublet not required, **after 1st or 2nd line**	A phase II study to evaluate antitumor activity of oral cMET inhibitor Capmatinib (INC280) in adult patients with EGFR wild-type, advanced non-small cell lung cancer (NSCLC) after one or two prior lines of systemic therapy for advanced/metastatic disease as measured by overall response rate (ORR). The study will also evaluate safety and pharmacokinetics of INC280. **INC 280A2201**
Small Cell Lung Cancer	
Must have had no more than 4 cycles of Platinum-based therapy with no evidence of disease progression.	Phase 3 Placebo Controlled Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer. **Abbvie M16-298 (MERU) PI - Segota (CRA - Kathy)**
Renal Cell Cancer	
Newly diagnosed high risk RCC, ≥ T2/ T any N where radical/partial nephrectomy planned	A Phase 3 Randomized Study Comparing PERIoperative Nivolumab Vs Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy **ECOG EA8143 (PROSPER-RCC) (CRA - Any CRA)**
Urothelial	
No PD-1 positive requirement with recurrence ≥ 12 months	A Phase 3, Open-label, Randomized Study of Nivolumab Combined With Ipilimumab Versus Standard of Care Chemotherapy in Participants With Previously Untreated Unresectable or Metastatic Urothelial Cancer **BMS CA209-901 PI - Azzi (CRA - Eileen/Sheryl)**
MDS, AML, CMML	
Previously treated/untreated MDS; with de novo or secondary MDS. Includes all French, American and British subtypes	A Phase 3, Randomized, Open-Label, Crossover Study of ASTX727 (Cedazuridine and Decitabine Fixed-Dose Combination) versus IV Decitabine in Subjects with Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML) **Astex ASTX727-02 PI - Drew (CRA - Sheryl)**
MDS, AML, Idiopathic cytopenia of unknown significance	The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry **Connect® MDS and AML - PI Drew (CRA - Kathy)**
Observational	
Cohorts *1. **HNSCC** 1st line metastatic/locally advanced 2nd line metastatic/locally advanced* *2. **Triple Negative Breast Cancer** A 1st line metastatic/locally advanced B ≥2nd line metastatic/locally advanced* *3. **NSCLC** A ≥2nd line Stage 3B or 4* *4. **Epithelial Ovarian** A 2nd line platinum resistant Stage 3 or 4 B 2nd line platinum sensitive Stage 3 or 4 C ≥3rd line platinum sensitive Stage 3 or 4* *5. **Colorectal Cancer** A 1st line Stage 4 B Recurrent or progressive disease following treatment w/both oxaliplatin- and irinotecan containing regimens*	Sensitivity Assay study - CANscriptTM Clinical Outcomes in a Real-World Setting (ANCERS)–2: A Prospective, Multicenter, Observational Study Examining the Clinical Utility of CANscriptTM in Routine Clinical Practice **Mitra Biotech MIT-201701 (ANCERS) PI - Segota (CRA - Kathy/Sheryl)** **PENDING**
Cancer Patients and Their Relatives	
Any Cancer Type	Molecular Genetics Studies of Cancer Patients and Their Relatives **CITY OF HOPE PI - Segota (CRA - Eileen)**

CONTACTS

For a Physician Appointment Call:
954-267-7700

Leonard Seigel, MD
Ena Segota, MD
David Drew, MD
Omar Rashid, MD
Georges Azzi, MD
Delia Constanza Guaqueta, MD
Michel Velez, MD
Dale Wyville, PA-C, MMS
Alice Gordon, PA-C, MMS

For Research Information Call:

Diana Christie, PharmD 954-776-3036
Eileen Georgi, RN, MSN 954-267-7748
Kathy McTague, RN, OCN 954-267-7718
Sheryl Llewellyn, RN, OCN 954-267-8528

Match Study Sub-Studies open to enrollment as of 08/20/2018

Arm	Target - Drug - Exceptions
A	EGFR activating mutations (0.05% frequency) Drug: Gilotrif® (afatinib) Exceptions: small cell or non-small cell lung cancer
C2	MET exon 14 deletion (0.61% frequency) Drug: Xalkori® (crizotinib) Exceptions: none
E	EGFR T790M (with/without an activating mutation) or rare activating mutations of EGFR (0.11% frequency) Drug: AZD9291 Exception: non-small cell lung cancer
F	ALK translocations (0.03% frequency) Drug: Xalkori® (crizotinib) Exceptions: non-small cell lung cancer or anaplastic large-cell lymphoma
G	ROS1 translocations (0.05% frequency) Drug: Xalkori® (crizotinib) Exception: non-small cell lung cancer with ROS1 rearrangements
J	HER2 amplification (1.49% frequency) Drugs: Herceptin® (trastuzumab) and Perjeta® (pertuzumab) Exceptions: breast cancer, colorectal cancer, gastric (stomach) cancer, or cancers where the food pipe (esophagus) meets the stomach
K1	FGFR amplification (1.86% frequency) Drug: erdafitinib Exceptions: transitional cell carcinoma of the bladder and/or urothelial tract
K2	FGFR mutations or fusions (1.00% frequency) Drug: erdafitinib Exceptions: transitional cell carcinoma of the bladder and/or urothelial tract
L	mTOR mutations (0.31% frequency) Drug: TAK-228 (formerly MLN0128) Exceptions: none
M	TSC1 or TSC2 mutations (1.11% frequency) Drug: TAK-228 (formerly MLN0128) Exceptions: none
S2	GNAQ or GNA11 mutations (0.16% frequency) Drug: Mekinist™ (trametinib) Exception: uveal melanoma
T	Smoothened (SMO) or patched 1 (PTCH1) mutations (0.42% frequency) Drug: Erivedge® (vismodegib) Exception: basal cell skin cancer
V	cKIT mutations (0.11% frequency) Drug: Sutent® (sunitinib malate) Exceptions: gastrointestinal stromal tumors (GIST), renal cell carcinoma, or pancreatic neuroendocrine tumors
Z1E	NTRK fusions (0.10% frequency) Drug: larotrectinib Exceptions: none
Z1F	PIK3CA (3.47% frequency) Drug: copanlisib Exceptions: indolent non-Hodgkin's lymphoma, diffuse large B cell lymphoma, or HER2-positive breast cancer
Z1G	PTEN loss by Immunohistochemistry without PIK3CA mutations (1.93% frequency) Drug: copanlisib Exceptions: indolent non-Hodgkin's lymphoma, diffuse large B cell lymphoma, or HER2-positive breast cancer
Z1H	PTEN (deleterious) seq result and PTEN expression by immunohistochemistry (1.75% frequency) Drug: copanlisib Exceptions: indolent non-Hodgkin's lymphoma, diffuse large B cell lymphoma, or HER2-positive breast cancer
Z1J - *pending*	TP53 mutation and MYC amplification (frequency unavailable) Drug: AZ1775
Z1K - *pending*	AKT mutations (0.77% frequency) Drug: ipatasertib
Z1L - *pending*	Non-V600 BRAF mutations (0.80% frequency) Drug: ulixertinib (BVD-523)
Z1M - *pending*	dMMR status (1.51% frequency) Drug: Opdivo® (nivolumab) and BMS-986016 (a LAG3 inhibitor)