Clinical Trial Flow Charts
Open and Pending Clinical Trials
10/21/2019

Oncology Trials

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Contact Carol Webb for questions, concerns, or updates at cwebb2@kumc.edu or 913-945-5793
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GI Associate Project Director: Benjamin Roberts
Early Phase Project Director: Adam AlDouri

- **GI Cancers**
- **Anal**
  - EA2165
    - HSC: 143196
    - PI: Kasi
    - Nivolumab after Combined Modality Therapy in Treating Patients With High Risk Stage II-IIIB Anal Cancer
    - WW, MCA
  - ETCTN 9673
    - HSC: 144041
    - PI: Kasi
    - Nivolumab or w/o Ipilimumab in Treating Patients With Refractory Metastatic Anal Cancer & Bowel Obstruction
    - WW

- **Bowel Obstruction**
  - S1316
    - HSC: 03516
    - PI: Al-Kasspooles
    - Surgery or Non-Surgical mgmt. in Pts W/ Intra-Abdominal Cancer & Bowel Obstruction
    - WW, CRC, KUH Consent

- **Prevention**
  - IIT: 2018Omeg3-CRC-Prev
    - HSC: 142925
    - PI: Saeed
    - Omega 3 Fatty Acids in CRC Prevention in Pts w/ Lynch Syndrome COLYNE
    - WW
  - NRG-G002
    - HSC: 143193
    - PI: Lominska
    - Veliparib, Pembrolizumab, & Combo Chemo in Pts W/ Locally Adv. Rectal Cancer
    - CRC, WW Consent

- **Neo Adj.**
  - IIT-2017-Cabozant-DurvaGI
    - HSC: 141879
    - PI: Saeed
    - Cabozantinib in combo w/ Durvalumab in Treatment of Met. CRC
    - WW

- **Adjuvant**
  - IIT-2016-MA-GI-MelphVMit-HIPEC
    - HSC: 141842
    - PI: Kasi
    - Trastuzumab & Pertuzumab compared to Cetuximab and Irinotecan (CETIRI) in ad/met CRC w/ HER-2 amplification
    - CRC, WW Consent

- **Adv./Met.**
  - NRG-G004-S1610
    - HSC: 141842
    - PI: Saeed
    - Bevacizumab & pertuzumab (TP) compared to cetuximab and irinotecan (CETIRI) in ad/met CRC w/ HER-2 amplification
    - CRC, WW, CCP, MCA

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GYN Cancers

Ovarian/ Peritoneal/ Fallopian

1st line

Recurrent

Plat. Sensitive

Platinum Resistant

1st line

GOG-3020 ATHENA
HSC: 142720
Pl: Jewell
Ovarian Cancer Pts Evaluating Rucaparib & Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemo

GOG-0016
HSC: 143483
Pl: Jewell
Pembrolizumab & Epacadostat in Pts w/ Recurrent, Persistent, or Progressive Ovarian Clear Cell Carcinoma

NRG-GY009
HSC: 142774
Pl: Jewell
Pegylated Liposomal Doxorubicin Hydrochloride w/ Atezolizumab and/or Bevacizumab in Treating pts w/ Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal CA

VB-111-701
HSC: 143198
Pl: Jewell
VB-111 With Paclitaxel vs Paclitaxel for Tx of Recurrent Platinum-Resistant Ovarian Cancer (OVAL)

ESR-16-12372/GYN 1842
HSC: tba
Pl: Jewell
Tisotumab Vedotin for Patients with Platinum-Resistant Ovarian Cancer with a Safety Run-in of a Dose-Dense Regimen

SGNTV-002
HSC: 143494
Pl: Jewell
Tisotumab Vedotin for Patients with Platinum-Resistant Ovarian Cancer with a Safety Run-in of a Dose-Dense Regimen

GOG-0264
HSC: tba
Pl: Jewell
Status: ERC approved 9.23
Paclitaxel and Carboplatin or Bleomycin Sulfate, Etoposide Phosphate, and Cisplatin in Treating Patients With Adv. or Recurrent Sex Cord-Ovarian Stromal Tumors

CO-338-097
HSC: tba
Pl: Jewell
Status: ERC approved 9.23
A Study to Evaluate Rucaparib in Combination With Nivolumab in Patients With Selected Solid Tumors (ARIES)

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GYN Referrals Email/Link:
KUCCCTOGYNTrialReferral@kumc.edu

Cervical / Vaginal

1st line

2nd line +

No trials

GCT1015-05
HSC: 143379
Pl: Jewell
Tisotumab Vedotin (HuMax-TF-ADC) in Combo w/ Other Agents in Subjects w/ Recurrent or Stage IVB Cervical Cancer

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EP Referrals Email/Link (at CRC)
KUCCCTOEarlyPhaseTrialReferral@kumc.edu

GYN Referrals Email/Link:
KUCCCTOGYNTrialReferral@kumc.edu
Lung Project Director: Chris Baierl
Early Phase Project Director: Adam AlDouri

Thoracic Cancer: Non-Small Cell

Localized
- Resectable
- Unresectable

Metastatic
- 1st line
- 2nd line +

ALCHEMIST:
- PI: Huang
- Study # HSC:
  - NRG-LU004 HSC: 144038 PI: Huang
  - EF-24 HSC: 144658 PI: Huang
- Status: 10.10 PRMC meeting
- Effect of Tumor Treating Fields (TTFields) (150 kHz) Conventional/W/OC Therapies for Treatment of Stage 4 NSCLC Following Platinum Failure (LUNAR)
- NKTR-214 in combo W/ Nivolumab

EA5163
- INSIGNA HSC: 143897 PI: Huang
- 1st line Pembrolizumab Alone or in combo W/ Pemetrexed & Carboplatin in Induction/Maintenance or Post progression in pts W/ Stage IV Non-squamous NSCLC
- CACZB88U2301
- CANOPY1 HSC: 144461 PI: Huang
- Status: 9.17 ICF to finance for review
- Pembrolizumab + Platinum-based Doublet Chemotherapy w/ or w/o Canakinumab in Prev. Untreated Locally Advanced or Met. Non-squamous & Squamous NSCLC

LungMAP
- HSC: 143485 PI: Huang
- Sub studies: S1900A HSC: 143488 S1800A HSC: 144150
- Master protocol to eval. biomarker driven therapies & immunotherapies in previously treated NSCLC (Lung-MAP Screening Study)

WW, CCP, MCA

TBA
- NKTR-16-214-02 HSC: 141187 PI: William
- Targeted Therapy for Treatment of Stage 4 NSCLC Following Platinum Failure (LUNAR)

R3767-ONC-1613
- HSC: 141280 PI: Jewell
- REG-3767 (Anti-LAG-3) w/ or w/o REG-N2810 (Anti-PD1) in Adv. Cancers

BTC: 143485
- PI: Huang
- Status: 9.17 ICF to finance for review
- Pembrolizumab + Platinum-based Doublet Chemotherapy w/ or w/o Canakinumab in Prev. Untreated Locally Advanced or Met. Non-squamous & Squamous NSCLC

CRC
- WW, CCP, MCA

WW
- NRG-LU004 HSC: 144038 PI: Huang
- Accelerated Hypofractionated or Conventionally Fractionated Radiotherapy & Durvalumab in Treating Patients With Stage II-III NSCLC

EP Referrals Email/Link (at CRC)
- KUCCCTOEaryPhaseTrialReferral@kumc.edu

Thoracic/Lung Referrals Email/Link:
- KUCCCTOLUNGTrialReferral@kumc.edu

TPS: 2004-08
- HSC: 142034 PI: Bananda
- Docetaxel + Pemetrexed in combo W/ Atezolizumab to pts W/ Locally Adv. or Met NSCLC

WW
- KUCCCTOLUNGTrialReferral@kumc.edu

TTFields
- tba
- EF-24 HSC: 144658 PI: Huang
- Status: 10.10 PRMC meeting
- Effect of Tumor Treating Fields (TTFields) (150 kHz) Conventional/W/OC Therapies for Treatment of Stage 4 NSCLC Following Platinum Failure (LUNAR)

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MIRI 10042
- HSC: 144674 PI: Mehta
- Status: 10.14 pending RSC approval
- A Phase II trial of AZD9291 (osimertinib) with or without bevacizumab in patients with EGFR positive NSCLC and brain metastases.

MIRI 10042
- HSC: 144674 PI: Mehta
- Status: 10.14 pending RSC approval
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MIRI 10042
- HSC: 144674 PI: Mehta
- Status: 10.14 pending RSC approval
- A Phase II trial of AZD9291 (osimertinib) with or without bevacizumab in patients with EGFR positive NSCLC and brain metastases.
AML: Newly Diagnosed

- Newly Dx or R/R
- Remission
- R/R

- AML: Newly Diagnosed
- Age ≥ 60
- 18+

- AML: Remission
- Eval. the Potential Impact of Renal Impairment on the PKs and Safety of CPX-351
- TROV-052
- HSC: 141828 Pl: Lin
- CPX-351-103
- HSC: 144144 Pl: Lin
- CPX-351-102
- HSC: 142684 Pl: Male
- GO40800
- HSC: 143649 Pl: Lin
- DS3032-A-U105
- HSC: 142680 Pl: Skikne
- IIT-2018-p53Atorva
- HSC: 142313 Pl: Baranda
- TP1-ALV-201
- HSC: 140505 Pl: Lin
- PTX-200-AML-05
- HSC: 140819 Pl: Dias

- AML: Remission
- Eval. the Potential Impact of Renal Impairment on the PKs and Safety of CPX-351
- TROV-052
- HSC: 141828 Pl: Lin
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- HSC: 142313 Pl: Baranda
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- HSC: 140505 Pl: Lin
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- HSC: 140819 Pl: Dias

- AML: R/R
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- TROV-052
- HSC: 141828 Pl: Lin
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- Hem Referrals Email/Link: KUCCCTOHemTrialReferral@kumc.edu
- Cell Therapy Referrals Email/Link: KUCCCTOCellTherapyTrialReferral@kumc.edu
Hematology Project Director: Marc Morrison
Early Phase Project Director: Adam AlDouri

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Hem Referrals Email/Link:
KUCCCTOHEMTrialReferral@kumc.edu

Cell Therapy Referrals Email/Link:
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EP Referrals Email/Link (at CRC)
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Hematology Project Director: Melody Kabrey
Early Phase Project Director: Adam AlDouri

Cell Therapy Referrals Email/Link:
KUCCCTOCellTherapyTrialReferral@kumc.edu
MDS

Untreated

Low/Intermediate

2012-407
RV-MDS-PI
03-0645
HSC:
142735
PI: Yacoub

Phase 1-2 Study of
Low Dose
ASTX727 (ASTX727
LD) in Lower
Risk
MDS

CRC, WW Consent

ASTX727-03
HSC:
142735
PI: Yacoub

High Risk

DS3032-A-U102
HSC:
143082
PI: Skikne

Lenalidomide
and Eltrombopag in
Low and Intermediate
Risk MDS

WW

CPX351-102
HSC:
142684
PI: Male

A Trial to Evaluate the
Potential Impact of
Renal Impairment on
the Pharmacokinetics
and Safety of CPX-351

CRC

04-30
(INSPIRE)
HSC:
03798
PI: Yacoub

Controlled Study of
Rigosertib
Versus Physician’s
Choice of Treatment
in MDS Pts
After Failure of an
HMA

WW, KUH

Prev. Treated

VICC Hem
16146
HSC:
141671
PI: Skikne

Pevonedistat
and Azacitidine in
MDS or MDS/MPN
Patients Who Fail Primary
Therapy With DNA Methyl
Transferase Inhibitors

WW

5001 -
APVO436
HSC:
142791
PI: Dias

Open-Label, Dose-
Escalation
Study of
APVO436 in
Patients
With R/R
AML or
High-Grade
MDS

WW

TBA

KUH, CRC, WW
Consent

Multi Diseases

No trials

CRC

24

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Hem Referrals Email/Link:
KUCCCTOHemTriReferral@kumc.edu

Cell Therapy Referrals Email/Link:
KUCCCTOCelTherapyTriReferral@kumc.edu
**Hematology Project Director:** Marc Morrison  
**Early Phase Project Director:** Adam AlDouri

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**MPN**

- **MF**
  - **1st line**
    - No trials
  - **2nd line**
    - **INCB 50465-201**  
      - HSC: 140410  
      - PI: Yacoub  
      - SL-401 in Patients with Advanced, High Risk Myeloproliferative Neoplasms  
      - WW, CRC
    - **INCB050465 in Combination With Ruxolitinib in Subjects With MF**  
      - HSC: 140515  
      - PI: Yacoub  
      - CRC, WW Consent
    - **IMG-7289 in Patients With MF**
      - HSC: 142110  
      - PI: Yacoub  
      - Fedratinib in DIPSS-I or High-Risk primary MF, post-PV, or post ET and previously treated with ruxolitinib.
    - **FEDR-MF-001**  
      - HSC: 143619  
      - PI: Yacoub  
      - MPN-RC118
    - **IMG-7289 in Patients With MF**
      - HSC: 142000  
      - PI: Yacoub  
      - MPN-RC118 submission
  - **1st line**
    - No trials
  - **2nd line**
    - **NP39761**
      - HSC: 141600  
      - PI: Yacoub  
      - I dasanutlin Monotherapy in Patients With Hydroxyurea-Resistant/Intolerant PV
    - **PTG-300-04**
      - HSC: 144246  
      - PI: Yacoub  
      - Status: 10.7 BRANY submission
      - Hepcidin Mimetic PTG-300 in Patients with Phlebotomy-Requiring PV
    - **MPN**
      - HSC: 144284  
      - PI: Yacoub  
      - Status: 10.17 financing confirming CF language

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**ET**

- **1st line**
  - No trials
  - **2nd line**
    - No trials

**PV**

- **1st line**
  - No trials
  - **2nd line**
    - **NP39761**
      - HSC: 141600  
      - PI: Yacoub  
      - I dasanutlin Monotherapy in Patients With Hydroxyurea-Resistant/Intolerant PV
    - **PTG-300-04**
      - HSC: 144246  
      - PI: Yacoub  
      - Status: 10.17 BRANY submission
      - Hepcidin Mimetic PTG-300 in Patients with Phlebotomy-Requiring PV
    - **MPN**
      - HSC: 144284  
      - PI: Yacoub  
      - Status: 10.17 financing confirming CF language

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**Mastocytosis**

- **BLU-285-2202**
  - HSC: 144128  
  - PI: Yacoub  
  - Status: 10.17 financing confirming CF language
  - Study to Evaluate Efficacy and Safety of Avapritinib (BLU-285), A Selective KIT Mutation-targeted Tyrosine Kinase Inhibitor, in Patients W/ Advanced Systemic Mastocytosis

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