

# Heme Malignancy Disease-Oriented Team

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## Clinical Research Treatment Trial Flowchart

**Clinical Research Manager:**  
Emiri Matsuda

**Clinical Research Coordinators:**  
Stephanie Osorio  
Judit Castellanos  
Kelsey McAbee  
Regan Dagenhart  
Harleen Mehrok  
Alice Ting

**Data Coordinators:**  
Heather Franson



# Newly diagnosed

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

## Front Line

**ETCTN 10538**  
 Venetoclax+ASTX727 (All oral therapy) for CMML, MDS/MPN with excess blasts  
 Accrual: 0/5  
 Coord: Kelsey McAbee  
 Mechanism: BCL-2 selective inhibitor

## Observational Study

**UCI 23-32**  
 Dissecting the mechanism of Interferon Alpha (IFN) response in MPN  
 Coord: N/A  
 Mechanism: observational study

## Supportive Care

**UCI 20-50**  
 N-Acetylcysteine in MPN to Improve Disease Markers & Symptoms  
 Accrual 11/27  
 Coord: Kelsey McAbee  
 Mechanism: Mucolytic agent (cysteine and GSH precursor)



# Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

## High-Risk

**UCI 22-151**  
 LYT-200 in patients w/ R/R AML or high-risk MDS  
 Accrual: 4/5  
 Coord: Stephanie Osorio  
 Mechanism: Galectin-9 monoclonal antibody

## Low-Risk

**UCI 21-239**  
 IRAK 1/4 inhibitor, R289, in patients w/ refractory or resistant lower-risk MDS  
 Accrual:1/5  
 Coord: Stephanie Osorio  
 Mechanism: IRAK1/4 inhibitor

## Molecularly-Driven

**UCI 23-113**  
 Oral GLB-001 in patients w/ R/R AML or high-risk MDS  
 Accrual: 0/7  
 Coord: Stephanie Osorio  
 Mechanism: Selective molecular glue degrader

## HSCT

## Newly diagnosed

Open to Accrual

Low Accruing

Pending Activation/Suspended

### Intensive

#### ETCTN-10596

SNDX-5613 + Daunorubicin and Cytarabine in Newly Diagnosed Acute Myeloid Leukemia (NPM1 Mutated/FLT3 Wildtype with Higher-Risk Features or MLL/KMT2A Rearranged)

Accrual: 0/5

Coord: Kelsey McAbee  
Mechanism: menin inhibitor

### Non-Intensive

#### FLT3 mutation

#### UCI 21-216

Gilteritinib+Venetoclax+Azacitidine in patients w/ FLT3 mutant AML not eligible for intensive induction chemotherapy

Accrual: 1/5

Coord: Stephanie Osorio  
Mechanism: FLT3 inhibitor

#### KMT2A-r/NPM1-m

#### UCI 23-44

Venetoclax/Azacitidine v.s Venetoclax+ KO-530 v.s cytarabine/daunorubicin (7+3)+ KO-539 in AML

Accrual: 0/6

Coord: Stephanie Osorio  
Mechanism: menin inhibitor

#### CD123+


#### UCI 19-138 (suspended)

IMGN632 as monotherapy or combination w/ Venetoclax and/or Azacitidine for patients w/ CD123-positive AML

Accrual: 2/5

Coord: Stephanie Osorio  
Mechanism: CD123 antibody

## Relapsed/Refractory

 Open to Accrual

 Low Accruing

 Pending Activation/Suspended
2<sup>nd</sup> Line+**UCI 22-151**

LYT-200 in patients w/ R/R AML or high-risk MDS

Accrual: 4/5

Coord: Stephanie Osorio  
Mechanism: Galectin-9 monoclonal antibody

**UCI 22-81**

HM43239 in patients w/ R/R AML

Accrual: 0/6

Coord: Stephanie Osorio  
Mechanism: FLT3 inhibitor

**UCI 23-154**

Ziftomenib combinations for the KMT2A-rearranged/NPM1 mutant R/R AML

Accrual: 0/5

Coord: Stephanie Osorio  
Mechanism: menin inhibitor

**UCI 23-113**

Oral GLB-001 in patients w/ R/R AML or high-risk MDS

Accrual: 0/7

Coord: Stephanie Osorio  
Mechanism: Selective molecular glue degrader

**UCI 24-48 (PRMC approval)**

DFP-10917+Venetoclax in R/R AML

Accrual: 0/5

Coord: Judit Castellanos  
Mechanism: Deoxycytidine nucleoside analogue (DNA synthesis inhibitor)

## Molecularly-Driven

# Relapsed/Refractory

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

## Molecularly-Driven

KMT2A-r/NPM1-m

UCI 23-44

Venetoclax/Azacitidine v.s  
Venetoclax+ KO-530 v.s  
cytarabine/daunorubicin (7+3)+  
KO-539 in AML

Accrual: 1/6

Coord: Stephanie Osorio  
Mechanism: menin inhibitor

## Salvage Therapy

UCI 19-93 (suspended)

DFP-10917 vs. non-intensive  
reinduction or intensive  
reinduction for AML patients  
in 2<sup>nd</sup> or 3<sup>rd</sup> salvage

Accrual: 11/12

Coord: Stephanie Osorio  
Mechanism: Nucleoside  
analog

Maintenance

High-Risk, HSCT

## Newly diagnosed

■ Open to Accrual  
 ■ Low Accruing  
 ■ Pending Activation/Suspended

### Ph+ only

#### EA9181

Steroids +TKI w/  
chemotherapy or  
Blinatumomab for BCR-ABL  
positive adult patients

Accrual 12/35

Coord: Harleen Mehrok  
Mechanism: BiTE binding to  
CD19 (on B-cell) and CD3 (on  
T-cells) and PD-1 inhibitor

### Ph- only

Age 55≥years or Age 40<55 years  
w/ severe comorbidity

#### UCI 21-98

Blinatumomab altering w/  
low-intensity chemotherapy  
vs. SOC for older adult  
patients

Accrual: 6/10

Coord: Judit Castellanos  
Mechanism: BiTE binding to  
CD19 (on B-cell) and CD3 (on  
T-cells) and PD-1 inhibitor

Age ≥ 18 years & < 40 years,  
CD22+ (≥ 20%)

#### A041501 (suspended)

Addition of Inotuzumab  
Ozogamicin to frontline  
therapy in young adults (18-  
39y/o)

Accrual: 10/15

Coord: Judit Castellanos  
Mechanism: conjugated anti-  
CD22 monoclonal antibody

### Observational

#### UCI 21-236

Addressing the Hispanic  
Cancer Disparity in B Cell  
Acute Lymphoblastic  
Leukemia  
Accrual: NA

Coord: NA  
Mechanism: Observational

Age 22-55 years & BMI <35kg/m2

#### UCI 22-125

Calaspargase pegol for tx of  
adults 22-55y/o w/ newly  
diagnosed Ph- ALL

Accrual: 0/5 (opened 4/22/24)

Coord: Judit Castellanos  
Mechanism: PEGylated  
conjugate L-asparaginase

Age 5 to <30 years & High Risk ALL

#### UCI 21-14

Levocarnitine for Asparaginase  
hepatotoxicity in ALL patients

Accrual: 0/5 (opened 11/3/23)

Coord: Judit Castellanos  
Mechanism: Oxidative stress  
reducer & inflammatory  
modulator

# Relapsed/Refractory

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended

## CR w/ MRD+

**UCI 20-34**  
 Outpatient Blinatumomab in adult patients w/ MRD of pre B-ALL in CR  
 Accrual: 2/5  
 Coord: Judit Castellanos  
 Mechanism: BiTE binding to CD19 (on B-cell) and CD3 (on T-cells) and PD-1 inhibitor

## Molecularly-Driven

### CD22+

**A041703**  
 Inotuzumab Ozogamicin followed by Blinatumomab for ph- CD22-positive newly diagnosed or R/R ALL patients  
 Accrual: 2/5  
 Coord: Judit Castellanos  
 Mechanism: antibody-drug conjugate combining a monoclonal antibody targeting CD22 on B-lymphoblast with the cytotoxic agents



## Newly diagnosed

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended

## High-Risk

**S1925**

Venetoclax+Obnutumab early intervention vs. delayed therapy in asymptomatic high-risk CLL/SLL

Accrual: 1/10

Coord: Stephanie Osorio  
Mechanism: BCL2 inhibitor +anti-CD20 monoclonal antibody

## Front Line


**UCI 23-156**

Sonrotoclax (BGB-11417) + Zanubrutinib (BGB-3111) v.s. Venetoclax +Obinutuzumab


Accrual: 1/7

Coord: Ali Saatchi  
Mechanism: BTK + BCL2 inhibition

## Relapsed/Refractory

 Open to Accrual

 Low Accruing

 Pending Activation/Suspended

Molecularly-Driven

Cell Therapy

2<sup>nd</sup> Line+UCI 21-209

LOXO-305 + Venetoclax and  
Rituximab vs. Venetoclax and  
Rituximab in previously treated  
CLL/SLL

Accrual: 2/3

Coord: Stephanie Osorio  
Mechanism: BTK inhibitor + BCL2  
inhibitor + CD20 marker

3<sup>rd</sup> Line+UCI 22-134

Oral AS-1763 in patients w/  
previously treated CLL/SLL or NHL

Accrual: 2/5

Coord: Emiri Matsuda  
Mechanism: BTK inhibitor for both  
wild-typ and C481S-mutant type

UCI 20-198 (suspended)

NX-2127, Bruton's tyrosine  
kinase degrader, in adults w/  
R/R B-cell malignancies

Accrual: 1/3

Coord: Stephanie Osorio  
Mechanism: BTK degrader +  
iMiD



# Relapsed/Refractory

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

2<sup>nd</sup> Line+

## UCI 23-167

Phase I- TERN-701 in patients  
w/CML

Accrual: 1/5

Coord: Kelsey McAbee

Mechanism: STAMP inhibitor



# Newly Diagnosed

Open to Accrual Low Accruing Pending Activation/Suspended

## Induction + Post ASCT- Maintenance

### UCI 23-70

The efficacy and safety of Idecabtagene Vicleucel + Lenalidomide v.s. Lenalidomide as single maintenance therapy  
\* Induction therapy + ASCT required

Accrual: 0/6 (opened 5/23/24)

Coord: Harleen Mehrok  
Mechanism: BCMA-directed autologous T-cell immunotherapy

## Front Line

### Bispecific

### UCI 23-158

Phase I/II Study of Linvoseltamab (Anti-BCMA X Anti-CD3 Bispecific Antibody) in Previously Untreated Patients with Symptomatic Multiple Myeloma

Accrual: 0/6 (opened 3/29/24)

Coord: Emiri Matsuda  
Mechanism: Bispecific antibody (BCMA x CD3)

### High-Risk

### ETCTN 10612

A Randomized Phase 2 Study of Daratumumab-Selinexor-Velcade-Dexamethasone (Dara-SVD) for High-Risk Newly Diagnosed Multiple Myeloma

Accrual: 0/5 (opened 4/25/24)

Coord: Stephanie Osorio  
Mechanism: selective inhibitor of nuclear export

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

## Maintenance

**S1803**

Daratumumab/rHuPH20 +  
lenalidomide vs. lenalidomide as post  
auto ASCT maintenance therapy

Accrual: 11/15

Coord: Judit Castellanos  
Mechanism: anti-CD38 monoclonal  
antibody

2<sup>nd</sup> Line+**UCI 22-190**

Teclistamab monotherapy vs.  
PVD or KD in patients received  
1-3 prior lines of therapy

Accrual: 3/3

Coord: Emiri Matsuda  
Mechanism: CD3 x BCMA BiTE

## Molecularly-Driven

3<sup>rd</sup> Line+

## CAR-T

**UCI 24-02 (PRMC approval)**

Descartes-15 in R/R MM

Accrual: 0/5

Coord: Judit Castellanos  
Mechanism: CAR-T, BCMA

**UCI 23-225 (IRB initial approval)**

Selinexor, Ruxolitinib and  
Methylprednisone in R/R MM

Accrual: 0/5

Coord: Stephanie Osorio  
Mechanism: SINE- XPO1  
inhibitor



Newly diagnosed

Open to Accrual

Low Accruing

Pending Activation/Suspended

Front Line

**UCI 23-17**  
Odronextamab (REGN1979) vs.  
investigator's choice in patient w/ FL

Accrual: 0/5 (3/20/24)

Coord: Regan Dagenhart  
Mechanism: Anti-CD20 x Anti-CD3  
bispecific antibody

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

### Cell Therapy

#### Molecularly-Driven

##### Outpatient

##### **UCI 22-96 (PRMC approval)**

Epcoritamab in outpatient setting for R/R DLBCL and classic FL (grade1-3a)

Accrual: 0/5

Coord: TBD  
Mechanism: IgG1-bispecific antibody

#### 3<sup>rd</sup> Line+

##### **UCI 22-134**

Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 2/5

Coord: Stephanie Osorio/Kelsey McAbee  
Mechanism: BTK inhibitor for both wild-typ and C481S-mutant type

##### **UCI 20-198 (suspended)**

NX-2127, Bruton's tyrosine kinase degrader, in adults w/ R/R B-cell malignancies

Accrual: 1/3

Coord: Regan Dagenhart  
Mechanism: BTK degrader + iMiD

#### Consolidation

##### **S2114**

Consolidation therapy following CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart  
Mechanism: bite/mab

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

## Cell Therapy

3<sup>rd</sup> Line+UCI 22-134Oral AS-1763 in patients w/  
previously treated CLL/SLL or NHL

Accrual: 2/5

Coord: Stephanie Osorio/Kelsey  
McAbeeMechanism: BTK inhibitor for both  
wild-typ and C481S-mutant typeUCI 20-198 (suspended)NX-2127, Bruton's tyrosine  
kinase degrader, in adults w/  
R/R B-cell malignancies

Accrual: 1/3

Coord: Regan Dagenhart  
Mechanism: BTK degrader +  
iMiD

## Molecularly-Driven

## EBV+

UCI 21-04Nanatinostat + Valganciclovir in  
patients w/ EBV+ R/R lymphomas

Accrual: 1/2

Coord: Regan Dagenhart  
Mechanism: selective HDAC class I  
inhibitor



Relapsed/Refractory

Open to Accrual Low Accruing Pending Activation/Suspended

3rd Line+

Cell Therapy

Molecularly-Driven

UCI 22-134

Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 2/5

Coord: Stephanie Osorio/ Kelsey McAbee

Mechanism: BTK inhibitor for both wild-typ and C481S-mutant type



Newly diagnosed

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

75 y/o Older

**S1918**  
R-miniCHOP w/ or w/o oral Azacitidine in patients 75 y/o or older  
Accrual: 3/10  
Coord: Regan Dagenhart  
Mechanism: Oral hypomethylating agent

## Relapsed/Refractory

■ Open to Accrual
 ■ Low Accruing
 ■ Pending Activation/Suspended

## Primary Relapsed/Refractory

**UCI 21-225 (suspended)**

Glofitamab+ R-ICE in patients w/  
R/R transplant eligible DLBCL

Accrual: 10/10

Coord: Regan Dagenhart  
Mechanism: T-cell bispecific  
antibody targeting CD20 (B-cell) and  
CD3ε chain T-cell)

## Cell Therapy- CRS mgmt

UCI 23-193 (IRB initial approval)  
CTO1681 for the Prevention and  
Treatment of CRS in Patients with  
DLBCL receiving Chimeric Antigen  
Receptor T-Cell Therapy

Accrual: 0/5

Coord: Judit Castellanos  
Mechanism: PGE2 & PG12 agonist

## Secondary Relapsed/Refractory

**UCI 20-126**

CB-010, CRISPR-edited  
allogeneic anti-CD19 CAR-T  
cell therapy

Accrual: 5/7

Coord: Emiri Matsuda  
Mechanism: anti-CD19  
**CHIMERIC ANTIGEN  
RECEPTOR**

## Outpatient

**UCI 22-96 (PRMC approval)**

Epcoritamab in outpatient  
setting for R/R DLBCL and  
classic FL

Accrual: 0/5

Coord: TBD  
Mechanism: IgG1-bispecific  
antibody

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

Molecularly-Driven

## Tertiary Relapsed/Refractory

UCI 20-198 (suspended)

NX-2127, Bruton's tyrosine kinase  
degrader, in adults w/ R/R B-cell  
malignancies

Accrual: 1/3

Coord: Regan Dagenhart

Mechanism: BTK degrader + iMiD

S2114

Consolidation therapy  
following CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart

Mechanism: bite/mab



# Relapsed/Refractory

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

Molecularly-Driven

Basket study

Newly diagnosed

COG ANHL1931

Nivolumab + chemo-immunotherapy

Accrual: 2/5

Coord: Regan Dagenhart

Mechanism: PD1 inhibitor

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

Relapsed/Refractory

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended

Consolidation

Consolidation therapy following  
CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart  
Mechanism: bite/mab

Molecularly-Driven

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

### Cell Therapy

#### UCI 23-114

Safety and Efficacy of IMPT-314, a CD19/20 Bispecific Chimeric Antigen Receptor (CAR) T Cell Therapy in B-cell NHL

Accrual: 1/7

Coord: Kelsey McAbee

Mechanism: CD19/20 bispecific CAR

### 3<sup>rd</sup> line+

#### UCI 22-134

Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 2/5

Coord: Stephanie Osorio/ Kelsey McAbee

Mechanism: BTK inhibitor for both wild-typ and C481S-mutant type

#### UCI 20-198 (suspended)

NX-2127, Bruton's tyrosine kinase degrader, in adults w/ R/R B-cell malignancies

Accrual: 1/3

Coord: Regan Dagenhart

Mechanism: BTK degrader + iMiD

### Molecularly-Driven





Relapsed/Refractory

■ Open to Accrual   ■ Low Accruing   ■ Pending Activation/Suspended

Molecularly-Driven

## Relapsed/Refractory

### 2<sup>nd</sup> Line+

#### UCI 21-224

KT-333 in R/R lymphomas,  
LGLL and solid tumors

Accrual: 0/5 (opened  
11/9/23)

Coord: Regan Dagenhart  
Mechanism: STAT3 degrader

### 3<sup>rd</sup> Line+

#### UCI 21-99

ONO-4685 given as  
monotherapy

Accrual: 1/10

Coord: Regan Dagenhart  
Mechanism: CD3-bispecific  
antibody targeting PD-1

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

## Molecularly-Driven



Supportive Care

**UCI 14-03**  
 Role of Inflammation in the Pathogenesis of Myeloproliferative Neoplasm

**UCI 15-65**  
 Effect of candidate blood cancer therapies on normal human lymphocytes

Long-Term FU

**UCI 21-184**  
 Long-term safety of CAR-T inpatient w/ heme malignancies  
 Accrual: 2/5  
 Coord: Emiri Matsuda

**UCI 21-90**  
 Risk-ADAPTEd conditionin regimen for AHST  
 Accrual: 8/48  
 Coord: Heme coordinators



## Polycythemia vera

### UCI 21-204

ISIS702843 in patients w/ PD-PC

Mechanism: Antisense oligonucleotide specific for human transmembrane protease serine 6

Accrual: 1/5

Coord: Kelsey McAbee

## HSCT Transplant

### UCI 22-188

Prospective evaluation of CMV-TCIP directed Letemovir ppx after AHCT

Coord: Emiri Matsuda  
Mechanism: anti-CMV