

# Heme Malignancy Disease-Oriented Team

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## Clinical Research Treatment Trial Flowchart

**Clinical Research Manager:**  
Blake Johnson

**Clinical Research Coordinators:**  
Stephanie Osorio  
Judit Castellanos  
Kelsey McAbee  
Regan Dagenhart  
Harleen Mehrok  
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**Data Coordinators:**  
Heather Franson  
Neha Ashraf  
An To

## 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 13/27

Coord: Kelsey McAbee  
Mechanism: Mucolytic agent (cysteine and GSH precursor)



Newly diagnosed

High-Risk

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

Low-Risk

Molecularly-Driven

HSCT

## 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: 5/8

Coord: Stephanie Osorio

Mechanism: Galectin-9 monoclonal antibody

#### UCI 23-113

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

Accrual: 2/7

Coord: Stephanie Osorio

Mechanism: Selective molecular glue degrader

### 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

## Newly diagnosed

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

### Intensive

#### ETCTN-10596 (SUSPENDED)

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

#### 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: 6/10

Coord: Stephanie Osorio  
 Mechanism: menin  
 inhibitor

#### ETCTN-10630

Ladademstat in Combination with  
 Venetoclax and Azacitidine in  
 Patients with Post MDS  
 Transformation to AML

Accrual: 1/7

Coord: Stephanie Osorio  
 Mechanism: LSD1 inhibitor

#### FLT3 mutation

#### UCI 21-216

Giltertinib+Venetoclax+Azac  
 itidine in patients w/ FLT3  
 mutant AML not eligible for  
 intensive induction  
 chemotherapy

Accrual: 2/5

Coord: Stephanie Osorio  
 Mechanism: FLT3 inhibitor

## Relapsed/Refractory



Open to Accrual



Low Accruing



Pending Activation/Suspended

Molecularly-Driven

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

#### UCI 23-113

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

Accrual: 1/7

Coord: Stephanie Osorio  
Mechanism: Selective  
molecular glue degrader

#### UCI 22-151

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

Accrual: 5/8

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 24-48

DFP-10917+Venetoclax in R/R  
AML

Accrual: 3/5

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

#### UCI 23-154

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

Accrual: 0/5

Coord: Stephanie Osorio  
Mechanism: menin inhibitor

## 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: 6/10

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 13/35

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

### Ph- only

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

#### UCI 22-125 (closed to accrual)

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

Accrual: 0/5

Coord: Judit Castellanos  
Mechanism: PEGylated  
conjugate L-asparaginase

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 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

Age ≥ 50 years & CD22+ (≥ 20%)

#### A042001

Inotuzumab Ozogamicin &  
Lower Dose Chemotherapy Plus  
Blinatumomab for Older Newly  
Dx Adults

Accrual: 0/7

Coord: Judit Castellanos  
Mechanism: antibody-drug  
conjugate & a monoclonal  
antibody targeting CD22



## Relapsed/Refractory

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

### Molecularly-Driven

CR w/ MRD+

CD22+ (≥ 20%)

#### **A041703**

Inotuzumab Ozogamicin followed by Blinatumomab for ph- CD22-positive newly diagnosed or R/R ALL patients

Accrual: 2/5 (only open for R/R)

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: 4/10

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: 3/7

Coord: Kelsey McAbee  
Mechanism: BTK + BCL2 inhibition

## Relapsed/Refractory

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

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

Accrual: 4/9

Coord: Kelsey McAbee

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

UCI 24-12

Study to Evaluate the BTK Degradar,  
ABBV-101, in Participants With B-cell  
Malignancies

Accrual: 0/5

Coord: TBD

Mechanism: BTK inhibitor/f ABBV-  
101 monotherapy

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

2<sup>nd</sup> Line+

Molecularly-Driven

Cell Therapy

## Relapsed/Refractory

2<sup>nd</sup> Line+UCI 23-167Phase I- TERN-701 in patients  
w/CML

Accrual: 2/5

Coord: Kelsey McAbee  
Mechanism: STAMP inhibitor

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

## Newly Diagnosed

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

Post ASCT

## 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: 1/6 (opened 3/29/24)

Coord: Stephanie Osorio  
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: 3/5 (opened 4/25/24)

Coord: Stephanie Osorio  
Mechanism: selective inhibitor of  
nuclear export

## Relapsed/Refractory

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

Molecularly-Driven

Maintenance

3<sup>rd</sup> Line+

CAR-T

UCI 24-02

Descartes-15 in R/R MM

Accrual: 3/5

Coord: Judit Castellanos  
Mechanism: CAR-T, BCMA

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

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

Accrual: 3/6

Coord: Alice Ting  
Mechanism: CD3 x BCMA BiTE

## Relapsed/Refractory

3<sup>rd</sup> Line+

CAR-T

ALLIANCE-A062102

Iberdomide Maintenance  
Therapy Following Idecabtagene  
Vicleucel CAR-T in R/R MM  
Accrual: 0/5

Coord: Judit Castellanos  
Mechanism: cereblon (CRBN)  
modulating agent

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

Molecularly-Driven

2<sup>nd</sup> Line+

Maintenance

## 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

#### SWOG 2308

MOSUNETUZUMAB VS. RITUXIMAB  
FOR LOW TUMOR BURDEN  
FOLLICULAR LYMPHOMA

Accrual: 0/5

Coord: Stephanie Osorio/Judit  
Castellanos  
Mechanism: Anti-CD20 IgG1 kappa  
antibody



## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

### Cell Therapy

#### Molecularly-Driven

##### Outpatient

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

##### UCI 22-134

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

Accrual: 4/9

Coord: Stephanie Osorio/Kelsey  
McAbee

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

#### Consolidation

##### S2114

Consolidation therapy following  
CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart  
Mechanism: bite/mab

## Relapsed/Refractory

2+ Lines

### UCI 24-12

Study to Evaluate the BTK Degradar, ABBV-101, in Participants With B-cell Malignancies

Accrual: 0/5

Coord: TBD

Mechanism: BTK inhibitor/f ABBV-101 monotherapy

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

Cell Therapy

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

### Molecularly-Driven

EBV+

#### 2 + Lines

##### UCI 24-12

Study to Evaluate the BTK Degradar, ABBV-101, in Participants With B-cell Malignancies

Accrual: 0/5

Coord: TBD

Mechanism: BTK inhibitor/f ABBV-101 monotherapy

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

##### UCI 22-134

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

Accrual: 4/9

Coord: Stephanie Osorio/Kelsey McAbee

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

## Relapsed/Refractory

Open to Accrual

Low Accruing

Pending Activation/Suspended

Cell Therapy

Molecularly-Driven

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

#### UCI 22-134

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

Accrual: 4/9

Coord: Stephanie Osorio/ Kelsey  
McAbee

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

### 2+ Lines

#### UCI 24-12

Study to Evaluate the BTK  
Degradar, ABBV-101, in  
Participants With B-cell  
Malignancies

Accrual: 0/5

Coord: TBD

Mechanism: BTK inhibitor/f ABBV-  
101 monotherapy

## 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: 5/10

Coord: Regan Dagenhart  
Mechanism: Oral  
hypomethylating agent

## Relapsed/Refractory

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

### Primary Relapsed/Refractory

#### 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: 1/5

Coord: Judit Castellanos  
Mechanism: PGE2 & PGI2 agonist

### Secondary Relapsed/Refractory

#### **UCI 20-126**

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

Accrual: 5/7

Coord: Michael K.  
Mechanism: anti-CD19

**CHIMERIC ANTIGEN  
RECEPTOR**

Outpatient

## Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

## Molecularly-Driven

## Tertiary Relapsed/Refractory

S2114

Consolidation therapy  
following CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart  
Mechanism: bite/mab

## 2+ Lines

UCI 24-12

Study to Evaluate the BTK Degradar,  
ABBV-101, in Participants With B-cell  
Malignancies

Accrual: 0/5

Coord: TBD  
Mechanism: BTK inhibitor/f ABBV-101  
monotherapy

## Newly Diagnosed

### COG-AHOD2131 (IRB INITIAL APPROVAL)

Standard Therapy with  
Immuno-oncology Therapy  
for Newly Diagnosed Stage I  
and II Classical Hodgkin  
Lymphoma

Accrual: 0/5

Coord: Judit Castellanos/  
Stephanie Osorio

Mechanism:

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

Molecularly-Driven

Basket study



## 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

## Molecularly-Driven

### Consolidation

#### S2114

Consolidation therapy following  
CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart  
Mechanism: bite/mab

### 2+ Lines

#### UCI 24-12

Study to Evaluate the BTK  
Degradar, ABBV-101, in  
Participants With B-cell  
Malignancies

Accrual: 0/5

Coord: TBD  
Mechanism: BTK inhibitor/f ABBV-  
101 monotherapy

## Relapsed/Refractory

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

### Molecularly-Driven

#### 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: 2/7

Coord: Judit Castellanos  
Mechanism: CD19/20 bispecific CAR

#### 2+ Lines

##### UCI 24-12

Study to Evaluate the BTK Degradar, ABBV-101, in Participants With B-cell Malignancies

Accrual: 0/5

Coord: TBD  
Mechanism: BTK inhibitor/f ABBV-101 monotherapy

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

##### UCI 22-134

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

Accrual: 4/9

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

## Relapsed/Refractory

UCI 21-99

ONO-4685 given as  
monotherapy

Accrual: 4/10

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

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

Molecularly-Driven

## Relapsed/Refractory

3<sup>rd</sup> Line+UCI 21-99ONO-4685 given as  
monotherapy

Accrual: 4/10

Coord: Regan Dagenhart  
Mechanism: CD3-bispecific  
antibody targeting PD-1 Open to Accrual  Low Accruing  Pending Activation/Suspended

Molecularly-Driven

2<sup>nd</sup> Line+

## Allo-SCT Conditioning

### UCI 21-90

Risk-ADAPTEd conditioning regimen  
for AHSCT

Accrual: 18/48

Coord: Heme CRCs

## Allo-SCT Supportive Care

### UCI 22-188

Prospective evaluation of CMV-TCIP  
directed Letemovir ppx after AHCT

Accrual: 10/50

Coord: Heme CRCs

## Auto-SCT Maintenance



## CAR-T

### UCI 20-126

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

Accrual: 5/7

Coord: Michael K.

Mechanism: anti-CD19 CAR-T

### UCI 23-114

Safety & Efficacy of IMPT-314, a CD19/20 Bispecific CAR-T in Participants with R/R B-Cell NHL

Accrual: 2/7

Coord: Judit Castellanos

Mechanism: CD19/20 bispecific CAR

### UCI 24-02

Descartes-15 in R/R MM

Accrual: 3/5

Coord: Mike K.

Mechanism: CAR-T, BCMA

## Supportive Care

### UCI 23-193

CTO1681 for the Prevention and Treatment of CRS in Patients with DLBCL receiving CAR-T Therapy

Accrual: 1/5

Coord: Alice Ting

Mechanism: PGE2 & PGI2 agonist

## Post CAR-T

### S2114

Consolidation Therapy Following CD19 CAR-T for R/R Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma

Accrual: 0/6

Coord: Regan Dagenhart

Mechanism: BiTE/mAb

### Alliance-A062102

Iberdomide Maintenance Therapy Following Ide-Cel CAR-T in R/R Multiple Myeloma

Accrual: 0/5

Coord: TBD

Mechanism: Cereblon (CRBN) modulating agent





## Supportive Care

### Long-Term FU

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

**UCI 21-184**  
Long-term safety of CAR-T  
inpatient w/ heme malignancies  
Accrual: 4/5  
Coord: Miranda Duron

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

**UCI 24-31**  
Long-Term Follow-up Protocol for  
Subjects Treated With Gene-  
Modified T Cells  
Accrual: 0/5  
Coord: TBD



 Open to Accrual  Low Accruing  Pending Activation/Suspended

Polycythemia vera

Other