

# Heme Malignancy Disease-Oriented Team

---

## Clinical Research Treatment Trial Flowchart

**Clinical Research Manager:**  
Blake Johnson

**Clinical Research Coordinators:**

Stephanie Osorio  
Judit Castellanos  
Kelsey McAbee  
Regan Dagenhart  
Harleen Mehrok  
Alice Ting  
Michael Kunicki  
Georgina Alvarez Diaz

**Data Coordinators:**

Heather Franson  
Neha Ashraf

## 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)



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: 1/7

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

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

**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: 2/6

Coord: Stephanie Osorio  
Mechanism: menin inhibitor

**ETCTN-10630**

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

Accrual: 0/7

Coord: Stephanie Osorio  
Mechanism: LSD1 inhibitor

**FLT3 mutation****UCI 21-216**

Giltertinib+Venetoclax+Azacitidine 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 (Suspended)

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: 2/5

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

Mutation+: KMT2A & NPM1

UCI 22-24

Phase I, first in human dose escalation and expansion of BMF-219, an oral, covalent, menin inhibitor in adults w/ AL and MM

Accrual: 1/5

Coord: Judit Castellanos  
Mechanism: menin 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

### UCI 24-95

Dose escalation and expansion of BMF-500, oral FLT3 Inhibitor in adults with R/R acute leukemia

Accrual: 0/5

Coord: Stephanie Osorio  
Mechanism: Covalent FLT3 inhibitor

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

## 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: 2/6

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 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/m<sup>2</sup>

#### UCI 22-125 (Suspended)

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 ≥ 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

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

### Observational

#### UCI 21-236

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

Coord: NA  
Mechanism: Observational

# Relapsed/Refractory

Open to Accrual

Low Accruing

Pending Activation/Suspended

CR w/ MRD+

## 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

CD20+ and/or CD19+

2+ line

Mutation+: KMT2A & NPM1

### UCI 22-24

Phase I, first in human dose escalation and expansion of BMF-219, an oral, covalent, menin inhibitor in adults w/ AL and MM

Accrual: 1/5

Coord: Judit Castellanos  
Mechanism: menin inhibitor

## 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: 2/10

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: 2/7

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: 2/5

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

■ 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: 2/5

Coord: Kelsey McAbee  
Mechanism: STAMP inhibitor



# 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: 1/5 (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

S1803

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

Accrual: 18/25

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: 3/6

Coord: Alice Ting  
Mechanism: CD3 x BCMA BiTE

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

UCI 22-24

Phase I, first in human dose escalation and expansion of BMF-219, an oral, covalent, menin inhibitor in adults w/ AL and MM

Accrual: 1/5

Coord: Judit Castellanos  
Mechanism: menin inhibitor



# Relapsed/Refractory

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

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

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

Relapsed/Refractory

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

Cell Therapy

Molecularly-Driven

3<sup>rd</sup> Line+

Consolidation

Outpatient

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

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

2 + Lines

3<sup>rd</sup> Line+

EBV+

**UCI 22-134**Oral 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 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

## 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: 2/5

Coord: Stephanie Osorio/ Kelsey  
McAbeeMechanism: 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





# 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 Degradator, 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: 2/5

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

**Molecularly-Driven**

# Relapsed/Refractory

3<sup>rd</sup> Line+

## UCI 21-99

ONO-4685 given as monotherapy

Accrual: 2/10

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: 15/48

Coord: Heme CRCs

### Allo-SCT Supportive Care

#### UCI 22-188

Prospective evaluation of CMV-TCIP directed Letemovir ppx after AHCT

Accrual: 9/50

Coord: Heme CRCs

### Auto-SCT Maintenance



■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

## 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