

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

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)



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

UCI 24-52 (ABANDONED)

SL-172154 (SIRP alpha-Fc-CD40L) in Combination with Azacitidine or with Azacitidine and Venetoclax

Accrual: 0/5

Coord: TBD
Mechanism: SIRP α -Fc-CD40L ARC™ fusion protein

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

UCI 24-52 (ABANDONED)

SL-172154 (SIRP alpha-Fc-CD40L) in
 Combination with Azacitidine or
 with Azacitidine and Venetoclax

Accrual: 0/5

Coord: TBD
 Mechanism: SIRP α -Fc-CD40L ARC™
 fusion protein

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

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

2nd Line+**UCI 24-52**

SL-172154 (SIRP alpha-Fc-CD40L) in Combination with Azacitidine or with Azacitidine and Venetoclax

Accrual: 0/5

Coord: TBD
Mechanism: SIRP α -Fc-CD40L ARC™ fusion protein

UCI 22-81 (Suspended)

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: 1/7

Coord: Stephanie Osorio
Mechanism: Selective molecular glue degrader

UCI 24-48

DFP-10917+Venetoclax in R/R AML

Accrual: 2/5

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

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

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

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 2nd or 3rd 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

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

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

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

3rd 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

2nd Line+

Molecularly-Driven

Cell Therapy



Relapsed/Refractory

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

2nd 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: 17/25

Coord: Judit Castellanos
Mechanism: anti-CD38 monoclonal antibody

2nd Line+UCI 22-190

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

Accrual: 3/3

Coord: Alice Ting
Mechanism: CD3 x BCMA BiTE

3rd Line+

CAR-T

UCI 24-02

Descartes-15 in R/R MM

Accrual: 2/5

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

UCI 23-225 (ABANDONED)

Selinexor, Ruxolitinib and Methylprednisone in R/R MM

Accrual: 0/5

Coord: Stephanie Osorio
Mechanism: SINE- XPO1 inhibitor



Relapsed/Refractory

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

3rd 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

2nd 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

Outpatient

UCI 22-96 (RRI Signoff)

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

Accrual: 0/10

Coord: TBD
Mechanism: IgG1-bispecific antibody

3rd 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

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

2+ Lines

UCI 24-01

Triple-specific T-Cell Engager 1A46 in Adult Patients with Advanced CD20 and/or CD19 Positive B-cell Hematologic Malignancies

Accrual: 0/5

Coord: TBD

Mechanism: recombinant, tri-specific T-cell activating immunoglobulin (Ig)G1-like antibody

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

EBV+

2 + Lines

UCI 24-01 (PRMC approval)

Triple-specific T-Cell Engager 1A46 in Adult Patients with Advanced CD20 and/or CD19 Positive B-cell Hematologic Malignancies

Accrual: 0/5

Coord: TBD

Mechanism: recombinant, tri-specific T-cell activating immunoglobulin (Ig)G1-like antibody

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

3rd 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

Cell Therapy

Molecularly-Driven

3rd 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

2+ Lines

UCI 24-01

Triple-specific T-Cell Engager 1A46
in Adult Patients with Advanced
CD20 and/or CD19 Positive B-cell
Hematologic Malignancies

Accrual: 0/5

Coord: TBD
Mechanism: recombinant, tri-
specific T-cell activating
immunoglobulin (Ig)G1-like
antibody

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
Azacitine 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

UCI 22-96 (RRI SIGNOFF)
Epcoritamab in outpatient setting for R/R DLBCL and classic FL

Accrual: 0/10

Coord: TBD
Mechanism: IgG1-bispecific antibody

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 24-01

Triple-specific T-Cell Engager 1A46 in
Adult Patients with Advanced CD20
and/or CD19 Positive B-cell Hematologic
Malignancies

Accrual: 0/5

Coord: TBD
Mechanism: recombinant, tri-specific T-
cell activating immunoglobulin (Ig)G1-like
antibody

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

3rd 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

3rd 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

2nd 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: 1/5

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