UCI ¹ Chao Family Comprehensive Cancer Center

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 An To

www.cancer.uci.edu

Myeloproliferative Neoplasm

Newly diagnosed

Front Line

ETCTN 10538

Venetoclax+ASTX727 (All oral therapy) for CMML, MDS/MPN with excess blasts

Accrual: 0/5

Coord: Stephanie Osorio Mechanism: BCL-2 selective inhibitor

UCI 24-121

ASTX030 in Subjects w/Myeloid Neoplasm or in Combo w/Venetoclax in Subjects w/AML or MDS

Accrual: 0/5

Coord: TBD Mechanism: cytidine deaminase inhibitor

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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

Low-Risk



HSCT

High-Risk

UCI 24-121

ASTX030 in Subjects w/Myeloid Neoplasm or in Combo w/Venetoclax in Subjects w/AML or MDS

Accrual: 0/5

Coord: TBD Mechanism: cytidine deaminase inhibitor

Myelodysplastic Syndrome



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

Non-Intensive

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: 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

UCI 24-121 ASTX030 in Subjects w/Myeloid Neoplasm or in Combo w/Venetoclax in Subjects w/AML or MDS

Accrual: 0/5

Coord: TBD Mechanism: cytidine deaminase 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: 7/10

Coord: Stephanie Osorio Mechanism: menin 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

UCI thChao Family Comprehensive Cancer Center Trial Flowchart May_2025





Open to Accrual

Low Accruing

Pending Activation/Suspended Molecularly-Driven

<u>UCI 23-113</u>

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

Accrual: 2/7

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: 1/6

Coord: Stephanie Osorio Mechanism: FLT3 inhibitor

<u>UCI 23-154</u>

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

Accrual: 2/5

Coord: Stephanie Osorio Mechanism: menin inhibitor

UCI &Chao Family Comprehensive Cancer Center UCI 24-48 DFP-10917+Venetoclax in R/R AML

Accrual: 4/5

Coord: Stephanie Osorio Mechanism: Deoxycytidine nucleoside analogue (DNA synthesis inhibitor)

Trial Flowchart May_2025

Molecularly-Driven

KMT2A-r/NPM1-m UCI 23-44 Venetoclax/Azacitidine v.s

Maintenance

Salvage Therapy

High-Risk, HSCT

Venetoclax+ KO-530 v.s cytarabine/daunorubicin (7+3)+

KO-539 in AML

Accrual: 7/10

Coord: Stephanie Osorio Mechanism: menin inhibitor



Newly diagnosed

EA9181

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

Coord: Judit Castellanos

Ph-only

Age \geq 18 years & < 40 years, Age 22-55 years & BMI <35kg/m2 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

Ph+ only

Accrual 14/35

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

Age 5 to <30 years & High Risk ALL

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

conjugate L-asparaginase

Mechanism: PEGylated

UCI 21-14 Levocarnitine for Asparaginase hepatoxicity in ALL patients Accrual: 0/5 (opened 11/3/23) Coord: Judit Castellanos Mechanism: Oxidative stress reducer & inflammatory modulator



Molecularly-Driven

CD22+ (≥ 20%)

<u>A041703</u>

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 Blymphoblast with the cytoxic agents

CR w/ MRD+



Newly diagnosed

High-Risk

<u>S1925</u>

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

Accrual: 4/10

Coord: Kelsey McAbee 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





2nd Line+

Molecularly-Driven

Cell Therapy

3rd 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

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee Mechanism: BTK inhibitor/f ABBV-101 monotherapy

Chronic Lymphocytic Leukemia

2nd Line+

UCI 23-167 Phase I- TERN-701 in patients w/CML

Accrual: 2/5

Coord: Kelsey McAbee Mechanism: STAMP inhibitor



Newly Diagnosed

Post ASCT

Front Line

Bispecific

<u>UCI 23-158</u>

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: Alice Ting 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

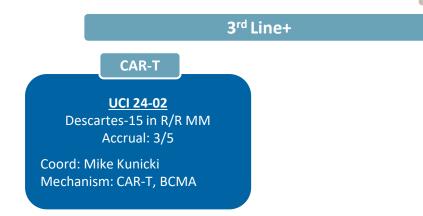
Accrual: 5/8 (opened 4/25/24)

Coord: Alice Ting Mechanism: selective inhibitor of nuclear export





Molecularly-Driven



2nd 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

Molecularly-Driven

2nd Line+

Maintenance

ALLIANCE-A062102

3rd Line+

CAR-T

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

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



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

<u>SWOG 2308</u> MOSUNETUZUMAB VS. RITUXIMAB FOR LOW TUMOR BURDEN FOLLICULAR LYMPHOMA

Accrual: 0/5

Coord: Stephanie Osorio/Judit Castellanos Mechanism: Anti-CD20 lgG1 kappa

Trial Flowchart May_2025



Cell Therapy

Molecularly-Driven

Outpatient

3rd 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

Consolidation

<u>S2114</u> Consolidation therapy following CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart Mechanism: bite/mab



Cell Therapy

2+ Lines

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee Mechanism: BTK inhibitor/f ABBV-101 monotherapy





Molecularly-Driven

Lymphoma Zone Marginal

2 + Lines

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee 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: 4/9

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



Cell Therapy

Molecularly-Driven

3rd 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

2+ Lines

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee Mechanism: BTK inhibitor/f ABBV-101 monotherapy



Newly diagnosed

75 y/o Older

<u>S1918 (SUSPENDED)</u> R-miniCHOP w/ or w/o oral Azacititine in patients 75 y/o or older

Accrual: 5/10

Coord: Regan Dagenhart Mechanism: Oral hypomethylating agent





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

<u>UCI 20-126</u> CB-010, CRISPR-edited allogeneic anti-CD19 CAR-T cell therapy

Accrual: 7/7

Coord: Michael K. Mechanism: anti-CD19 CHIMERIC ANTIGEN RECEPTOR

Outpatient

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Molecularly-Driven

Tertiary Relapsed/Refractory

<u>S2114</u> Consolidation therapy following CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart Mechanism: bite/mab

2+ Lines

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee Mechanism: BTK inhibitor/f ABBV-101 monotherapy

Newly Diagnosed

Molecularly-Driven

Basket study

COG-AHOD2131

Standard Therapy with Immuno-oncology Therapy for Newly Diagnosed Stage I and II Classical Hodgkin Lymphoma Accrual: 1/5 Coord: Judit Castellanos/ Stephanie Osorio Mechanism:



Basket study



Newly diagnosed

Open to Accrual Low Accruing Pending Activation/Suspended

COG ANHL1931 Nivolumab + chemoimmunotherapy

Accrual: 2/5

Coord: Regan Dagenhart Mechanism: PD1 inhibitor



Molecularly-Driven

Consolidation

<u>S2114</u> Consolidation therapy following CD19 CAR T-cell tx

Accrual: 0/6

Coord: Regan Dagenhart Mechanism: bite/mab

2+ Lines

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee Mechanism: BTK inhibitor/f ABBV-101 monotherapy



Molecularly-Driven

Cell Therapy

<u>UCI 23-114</u>

Safety and Efficacy of IMPT-314, a CD19/20 Bispecific Chimeric Antigen Receptor (CAR) T Cell Therapy in Bcell NHL Accrual: 3/7

Coord: Judit Castellanos Mechanism: CD19/20 bispecific CAR

2+ Lines

<u>UCI 24-12</u>

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

Accrual: 0/5

Coord: Kelsey McAbee 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: 4/9

Coord: Kelsey McAbee Mechanism: BTK inhibitor for both wild-typ and C481Smutant type



Molecularly-Driven

UCI 21-99 ONO-4685 given as monotherapy

Accrual: 4/10

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



Molecularly-Driven

2nd Line+

3rd Line+

UCI 21-99 ONO-4685 given as monotherapy

Accrual: 4/10

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



Auto-SCT Maintenance

Allo-SCT Conditioning

UCI 21-90 Risk-ADAPTed conditioning regimen for AHSCT

Accrual: 19/48

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

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CAR-T

UCI 20-126

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

Accrual: 7/7

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: 3/7

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

<u>UCI 23-193</u> 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

<u>S2114</u>

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

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Supportive Care

Long-Term FU

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

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

Coord: Miranda Duron

UCI 24-31

Long-Term Follow-up Protocol for Subjects Treated With Gene-Modified T Cells

Accrual: 0/5

Coord: TBD





HLH

UCI 23-189

Frontline Ruxolitinib with De-Intensified HLH-94 for Adults with Hemophagocytic Lymphohistiocytosis (HLH)

Accrual: 0/5

Coord: Stephanie Osorio

