UCI ¹ Comprehensive Cancer Center

Heme Malignancy Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

Clinical Research Manager: Blake Johnson

Clinical Research Coordinators: Emiri Matsuda Stephanie Osorio Judit Castellanos Kelsey McAbee Regan Dagenhart Harleen Mehrok Alireza Saatchi

Data Coordinators: Alice Ting Heather Franson

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Front Line

ETCTN 10538 Venetoclax+ASTX727 (All

oral therapy) for CMML, PDS/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 10/27

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



2nd Line+

<u>UCI 20-51</u>

IO-202 in R/R AML patients w/ monocytic differentiation and in <u>R/R CMML patients</u>

Accrual: 4/5

Coord: Stephanie Osorio Mechanism: LILRB4 antibody



UCI 22-151 LYT-200 in patients w/ R/R AML

<u>or high-risk MDS</u>

Accrual: 3/5

Coord: Stephanie Osorio Mechanism: Galectin-9 monoclonal antibody

HSCT

UCI 23-90 SAR445419 in high-risk myeloid malignancies undergoing HSCT

Accrual: 0/5

Coord: Emiri Matsuda Mechanism: off-the-shelf NK cells

Low-Risk

UCI 21-239 IRAK 1/4 inhibitor, R289, in patients w/ refractory or resistant lower-risk MDS

Accrual:0/5

Coord: Stephanie Osorio Mechanism: IRAk1/4 inhibitor

Molecularly-Driven

IDH

UCI 21-144 HMPL-306 in advanced hematological malignances w/ IDH mutations

Accrual: 0/5

Coord: Stephanie Osorio Mechanism: IDH1/2 inhibitor



Intensive

UCI 18-105 The combination of CPX-351 and Glasdegib in previously undertreated patients w/ AML w/ MDS related changes or therapy related AML

Accrual: 25/30

Coord: Kelsey McAbee Mechanism: Hedgehog pathway inhibitor+liposomal formulation of cytoxic chemotherapy Danorubicin & Cytarabine

Non-Intensive

FLT3 mutation

<u>UCI 21-216</u> <u>Giltertinib+Venetoclax+Azacitid</u> <u>ine in patients w/ FLT3 mutant</u> <u>AML not eligible for intensive</u> <u>induction chemotherapy</u>

Accrual: 1/5

Coord: Stephanie Osorio Mechanism: FLT3 inhibitor

CD123+

UCI 19-138

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

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

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Relapsed/Refractory

2nd Line+

UCI 22-151 LYT-200 in patients w/ R/R AML or high-risk MDS

Accrual: 3/5

Coord: Stephanie Osorio Mechanism: Galectin-9 monoclonal antibody

Leukemia

Myeloid

Acute

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

Molecularly-Driven

IDH UCI 21-144 HMPL-306 in advanced hematological malignances w/ IDH mutations

Accrual: 0/5

Coord: Stephanie Osorio Mechanism: IDH1/2 inhibitor

Menin

UCI 22-24 BMF-219 in patients w/ AL, DLBCL, MM, CLL/SLL

Accrual: 1/5

Coord: Judit Castellanos Mechanism: menin inhibitor

Maintenance

UCI 22-183 Galinpepimut-S (GPS) maintenance monotherapy vs. investigator's choice of best available therapy

Accrual: 0/5 (opened 11/09/23)

Coord: Stephanie Osorio Mechanism: WT-1 derived synthetic analog peptides

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 AMI

Accrual: 0/6

Coord: Stephanie Osorio Mechanism: menin inhibitor

High-Risk, HSCT

UCI 23-90 SAR445419 in high-risk myeloid malignancies undergoing HSCT

Accrual: 0/5

Coord: Emiri Matsuda Mechanism: off-the-shelf NK cells

Salvage Therapy

UCI 19-93

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

Newly diagnosed

Ph+ only

<u>EA9181</u> <u>Steroids +TIKI w/ chemotherapy</u> <u>or Blinatumomab for BCR-ABL</u> <u>positive adult patients</u>

Accrual 11/35

Coord: Judit Castellanos Mechanism: BiTE binding to CD19 (on B-cell) and CD3 (on Tcells) and PD-1 inhibitor UCI 21-98 Blinatumomab altering w/ lowintensity chemotherapy vs. SOC for older adult patients

Ph- only

Accrual: 5/6

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

> UCI 22-125 Calaspargase pegol for tx of adults 22-65y/o w/ newly diagnosed Ph- ALL

> > Accrual: 0/5

Coord: Judit Castellanos Mechanism: PEGylated conjugate L-asparaginase <u>A041501</u> <u>Addition of Inotuzumab</u> <u>Ozogamicin to frontline</u> <u>therapy in young adults (18-</u> 39y/o)

Ph+ or Ph-

Accrual: 10/15

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

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





CR w/ MRD+

UCI 20-34 Outpatient Blinatumomab in adult patients w/ MRD of pre B-ALL in

<u>CR</u>

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: 1/5

Coord: Judit Castellanos Mechanism: antibody-druf conjugate combining a monoclonal antibody tartgeting CD22 on B-lymphoblast with the cytoxic agents

Menin

UCI 22-24 BMF-219 in patients w/ AL, DLBCL, MM, CLL/SLL

Accrual: 1/5

Coord: Judit Castellanos Mechanism: menin inhibitor



High-Risk

<u>S1925</u>

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



ם. Leukem **Chronic Lymphocytic**

Molecularly-Driven

Menin UCI 22-24 BMF-219 in patients w/ AL, DLBCL, MM, CLL/SLL

Accrual: 1/5

Cell Therapy

UCI 21-19

MB-106 in patients w/ R/R CD20+

B-cell NHL or CLL

Accrual: 1/5

Coord: Judit Castellanos Mechanism: menin inhibitor

2nd Line+

<u>UCI 21-209</u>

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

Accrual: 1/3

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

3rd Line+

UCI 22-134 Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 1/5

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

UCI 20-198

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

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antigen receptor

Coord: Regan Dagenhart Mechanism: anti-CD20 chimeric

Relapsed/Refractory

2nd Line+

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

Accural: N/A

Coord: Stephanie Osorio Mechanism: STAMP inhibitor



Maintenance

Molecularly-Driven

2nd Line+

<u>S1803</u>

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

Accrual: 10/15

Coord: Judit Castellanos Mechanism: anti-CD38 monoclonal antibody

Menin

UCI 22-24 BMF-219 in patients w/ AL, DLBCL, MM, CLL/SLL

Accrual: 1/5

Coord: Judit Castellanos Mechanism: menin inhibitor UCI 22-190 Teclistamab monotherapy vs. PVD or KD in patients received 1-3 prior lines of therapy

Accrual: 2/3

Coord: Emiri Matsuda Mechanism: CD3 x BCMA BiTE





Front Line

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

Coord: Emiri Matsuda Mechanism: Anti-CD20 x Anti-CD3 bispecific antibody



Cell Therapy

UCI 21-19 MB-106 in patients w/ R/R CD20+ Bcell NHL or CLL

Accrual: 1/5

Coord: Regan Dagenhart Mechanism: anti-CD20 chimeric antigen receptor

UCI 22-01 Axicabtagene Ciloleucel vs. SOC in patients w/ R/R FL

Accrual: 0/5

Coord: Regan Dagenhart Mechanism: anti-CD19 CAR T-cell

3rd Line+

UCI 22-134 Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 1/5 (opened 11/21/23)

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

UCI 20-198

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: Emiri Matsuda Mechanism: bite/mab

Molecularly-Driven

UCI 21-04 Nanatinostat + Valganciclovir in

patients w/ EBV+ R/R lymphomas

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor

Cell Therapy

UCI 21-19 MB-106 in patients w/ R/R CD20+ B-cell NHL or CLL

Accrual: 1/5

Coord: Regan Dagenhart Mechanism: anti-CD20 chimeric antigen receptor

3rd Line+

UCI 22-134 Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 1/5

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

UCI 20-198

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

<u>UCI 21-04</u>

Nanatinostat + Valganciclovir in patients w/ EBV+ R/R lymphomas

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor

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Cell Therapy

3rd Line+

Molecularly-Driven

UCI 21-19 MB-106 in patients w/ R/R CD20+ B-cell NHL or CLL

Accrual: 1/5

Coord: Regan Dagenhart Mechanism: anti-CD20 chimeric antigen receptor UCI 22-134 Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 1/5

Coord: Emiri Matsuda Mechanism: BTK inhibitor for both wild-typ and C481S-mutant type UCI 21-04 Nanatinostat + Valganciclovir in patients w/ EBV+ R/R lymphomas

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor

75 y/o Older

<u>S1918</u>

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

Accrual: 3/10

Coord: Regan Dagenhart Mechanism: Oral hypomethylating agent





Primary Relapsed/Refractory

<u>UCI 21-225</u>

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

Accrual: 7/10

Coord: Regan Dagenhart Mechanism: T-cell bispecific antibody targeting CD20 (B-cell) and CD3 ϵ chain T-cell)

Secondary Relapsed/Refractory

UCI 21-19 MB-106 in patients w/ R/R CD20+ B-cell NHL or CLL

Accrual: 1/5

Coord: Regan Dagenhart Mechanism: anti-CD20 CHIMERIC ANTIGEN RECEPTOR <u>UCI 20-126</u> <u>CB-010, CRISPR-edited</u> <u>allogeneic anti-CD19 CAR-T</u> <u>cell therapy</u>

Accrual: 5/7

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



B-Cell Lymphoma Large Diffuse

Tertiary Relapsed/Refractory

UCI 22-24 BMF-219 in patients w/ AL, DLBCL, MM, CLL/SLL

Accrual: 1/5

Coord: Stephanie Osorio Mechanism: menin inhibitor <u>S2114</u> <u>Consolidation therapy</u> <u>following CD19 CAR T-cell tx</u>

Accrual: 0/6

Coord: Emiri Matsuda Mechanism: bite/mab

Molecularly-Driven

<u>UCI 21-04</u>

Nanatinostat + Valganciclovir in patients w/ EBV+ R/R lymphomas

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor

UCI 20-198 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

Basket study

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

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor





Newly diagnosed

Open to Accrual Low Accruing Pending Activation/Suspended

COG ANHL1931 Nivolumab + chemoimmunotherapy

Accrual: 1/5

Coord: Regan Dagenhart Mechanism: PD1 inhibitor



Relapsed/Refractory

Consolidation

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

Accrual: 0/6

Coord: Emiri Matsuda Mechanism: bite/mab

Molecularly-Driven

UCI 21-04

Nanatinostat + Valganciclovir in patients w/ EBV+ R/R lymphomas

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor



Relapsed/Refractory

Cell Therapy

UCI 21-19 MB-106 in patients w/ R/R CD20+ B-cell NHL or CLL

Accrual: 1/5

Coord: Regan Dagenhart Mechanism: anti-CD20 chimeric antigen receptor

3rd line+

UCI 22-134 Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL

Accrual: 1/5 (opened 11/21/23)

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

UCI 20-198 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

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

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor

Molecularly-Driven

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

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor



2nd Line+

UCI 21-224 KT-333 in R/R lymphomas, LGLL and solid tumors

Accrual: 0/5

Coord: Regan Dagenhart Mechanism: STAT3 degrader

3rd Line+

<u>UCI 21-99</u> ONO-4685 given as <u>monotherapy</u>

Accrual: 1/10

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

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Molecularly-Driven

<u>UCI 21-04</u>

Nanatinostat + Valganciclovir in patients w/ EBV+ R/R lymphomas

Accrual: 0/2

Coord: Regan Dagenhart Mechanism: selective HDAC class I inhibitor

UCI 21-144 HMPL-306 in advanced hematological malignances w/ IDH mutations

Accrual: 0/5

Coord: Stephanie Osorio Mechanism: IDH1/2 inhibitor

Supportive Care

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

Long-Term FU

UCI 21-184 Long-term safety of CAR-T inpatient w/ heme malignancies

Accrual: 2/5

Coord: Emiri Matsuda

UCI 15-65

Effect of candidate blood cancer therapies on normal human lymphocytes

UCI 21-90 Risk-ADAPTed conditionin regimen for AHSCT

Accrual: 4/48

Coord: Emiri Matsuda



Polycythemia vera

Basket study

HSCT Transplant

<u>UCI 21-204</u>

ISIS702843 in patients w/ PD-PC

Mechanism: Antisense oligonucleotide specific for human transmembrane protease serine 6

Accrual: 1/5 Coord: Kelsey McAbee UCI 22-188 Prospective evaluation of CMV-TCIP directed Letemovir ppx after AHCT

Coord: Emiri Matsuda Mechanism: anti-CMV



