

Leukemia Committee

Leadership

Chair:	Harry P. Erba, MD, PhD
Vice-Chair:	Anjali S. Advani, MD
Executive Officer:	Susan M. O'Brien, MD
Statisticians:	Megan Othus, PhD Anna Moseley, MS
Scientific Leadership	
Translational Medicine:	Jerald P. Radich, MD
Pathology:	David R. Head, MD
Cytogenetics Liaison:	Min Fang, MD, PhD
Designates	
Cancer Control:	Stephanie B. Tsai, MD
Data Coordinators:	Louise Highleyman Laura Kingsbury Matt Gospe
Oncology Research Professionals:	
CRA:	TBD
Nurse:	TBD
Patient Advocate:	Gail Sperling, MPH
Pharmaceutical Science:	Holly O. Chan, PharmD Ila M. Saunders, PharmD
Protocol Project Manager:	Sharon Palmer
Protocol Project Manager - MyeloMATCH:	Sarah Cantu
Clinical Trials Program Manager:	Mariah Norman, MS

Time/Location

Friday, May 12, 2023 10:00 am - 12:00 pm
Room: Garden Room (Atrium Lobby Level)

Agenda

AML/MDS Studies

Active Studies

CTSU/A041701, "A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy." Dr. Liesveld. Activated: 1/16/19. Temporarily closed to accrual 11/19/21

Closed Studies

S1612, "A Randomized Phase II/III Trial of "Novel Therapeutics" Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older." Drs. Michaelis, Walter, Assouline, et al. Activated: 12/22/17; Closed: 9/3/20.

S0919, "A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)." Dr. Advani. Re-Activated: 4/1/13; Closed: 9/15/17; Complete: 10/21/21.

S1203, "A Randomized Phase III Study of Standard Cytarabine Plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (NSC-701852) (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)." Drs. Garcia-Manero and Pagel. Activated: 12/15/12; Closed: 11/4/15; Complete: 3/29/22.

ALL Studies

Active Studies

S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani, Papadantonakis, and Yeung. Activated: 8/17/20.

CTSU/A041501, "A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL." Dr. Advani. Activated: 6/1/17. Temporarily closed to accrual: 5/24/22.

Developing Studies

S2306, "A Randomized Phase 2 Trial to Evaluate the Efficacy of Bcl-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma." Drs. O'Dwyer, Aldoss, Advani, and Stock.

S2307, "A Phase 1B Study Assessing the Safety and Activity of SNDX-5613 (revumenib) in Combination with Age-Modified Chemotherapy in Newly Diagnosed patients with KMT2Ar acute lymphoblastic leukemia (ALL) or acute leukemia with ambiguous lineage (ALAL)." Drs. Aldoss, Advani, and Stock.

Closed Studies

S0333, "A Phase II Study of Double Induction Chemotherapy for Newly Diagnosed Non-L3 Adult Acute Lymphoblastic Leukemia with Investigation of Minimal Residual Disease and Risk of Relapse Following Maintenance Chemotherapy." Drs. Forman and O'Donnell. Activated: 4/15/05; Closed: 11/1/09.

S1312, "A Phase I Study of Inotuzumab Ozogamicin in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with

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Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia, and Burkitt's Leukemia)." Drs. Advani and Liedtke. Activated: 4/1/14; Closed: 8/2/19.

S1318, "A Phase II Study of Blinatumomab and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphocytic Leukemia (ALL) and of Dasatinib, Prednisone and Blinatumomab for Patients \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL and Philadelphia-Chromosome-Like Signature (Ph-like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)." Drs. Advani and O'Dwyer. Activated: 1/12/15; Closed: 4/15/21.

CLL Studies

Active Studies

S1925, "Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL): EVOLVE CLL/SLL Study." Drs. Stephens, Hill, Pagel, et al. Activated: 12/14/20.

Closed Studies

CTSU/EA9161, "A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. Shadman. Activated: 1/3/19. Closed: 4/30/21.

CTSU/A041702, "A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (\geq 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Hill. Activated: 1/4/19. Closed: 1/4/19.

CML Studies

Closed Studies

S1712, "A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease." Drs. Sweet and Radich. Activated: 7/20/18. Closed: 10/20/22.

MyeloMATCH

Proposed Studies

MYELOMATCH, "Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Trials." Dr. Radich.

MM1YA-S01, "A Randomized Phase II Study of Novel Therapeutics in Younger Patients with High-Risk Acute Myeloid Leukemia." Drs. Shami and Lin.

MM10A-S02, "A Phase 2 Study of Targeted Agents with the Oral DNMT1 Inhibitor C-DEC (ASTX727) for the Treatment of TP53-Mutated Acute Myeloid Leukemia: A myeloMATCH treatment trial." Drs. Shallis, Sallman, and Zeidan.

MM10A-S03, "A Randomized Phase 2 trial of C-DEC, Venetoclax, and Enasidenib Compared with Azacitidine and Venetoclax for Newly Diagnosed Older Adults with IDH2 mutant AML: A myeloMATCH Treatment Trial." Drs. Borate and Huselton.

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Accrual from trial opening through 12/31/2022 by Institution and Study

	S1712	S1905	S1925	A041501	A041701	A041702	A041703	EA9161	EA9171	EA9181
Banner U Med Ctr - Tucson	-	-	-	-	-	5	-	4	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	1	-	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	1	3	4	-	5	-	-	-	-
Ca Res for the Ozarks NCORP	1	-	-	-	-	-	-	-	-	-
City of Hope CCC	-	3	1	-	-	-	-	-	-	-
CommonSpirit Hlth Res Inst	-	-	-	-	-	-	-	1	-	-
Dayton NCORP	-	-	-	-	-	1	-	2	-	-
Duke U - Duke Ca Inst LAPS	3	-	-	-	-	-	-	9	-	1
Fred Hutchinson Ca Res Ctr LAPS	1	3	-	-	-	-	-	9	-	-
Hawaii MU NCORP	6	-	-	-	-	-	-	-	-	3
Heartland Ca Res NCORP	5	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	2	-	4	3	-	1	-	-
Intermountain Med Ctr	-	-	-	2	-	-	-	-	-	-
Kaiser Permanente NCORP	-	-	-	-	-	8	-	32	-	-
Lahey Hospital and Med Ctr	-	-	-	-	-	1	-	-	-	-
Loyola U Med Ctr	1	-	1	-	-	1	-	2	-	1
Med U South Carolina MU NCORP	-	-	1	-	-	1	-	7	-	-
Michigan Ca Res Consort NCORP	1	-	4	-	-	1	-	-	-	-
Moffitt CC	16	-	-	-	-	-	-	-	-	-
Montana Ca Consort NCORP	1	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	1	-	-	-	-	-	-	1	-	-
Nevada Ca Res Foundation NCORP	2	-	-	-	-	3	-	5	-	-
New Mexico MU NCORP	3	-	-	-	-	-	-	1	-	-
Northwell Hlth NCORP	-	-	-	-	2	-	-	-	-	-
Northwestern U LAPS	-	-	-	3	1	2	-	-	-	4
Oregon Hlth and Science U	3	1	-	8	-	5	-	9	-	-
STCC at DHR Hlth Inst for Res and Dev	-	-	1	-	-	-	-	-	-	-
Salem Hospital	-	-	-	-	-	-	-	4	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	2	-	-
Stanford Ca Inst Palo Alto	-	-	-	8	-	11	-	29	-	-
UC Davis CCC LAPS	-	-	2	2	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	3	-	-	-	-	-	5
UC San Diego Moores CC	-	-	-	-	-	-	-	-	-	1
U Alabama Birm / Deep South RC LAPS	-	-	-	1	-	-	-	7	-	-
U Arkansas for Med Sciences	-	-	-	-	4	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	2	-	-	-	-	1	-	-	1
U Colorado CC LAPS	-	-	-	-	-	1	-	1	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	6	-	8	-	-
U Rochester LAPS	7	1	6	7	27	1	3	1	-	5
U Utah - Huntsman Ca Inst LAPS	7	-	9	1	-	5	-	22	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	4	-	3
Western States Ca Res NCORP	-	-	-	-	-	2	-	1	-	-
Yale U - Yale CC LAPS	-	-	-	5	-	3	-	10	2	-
ALLIANCE	13	2	7	-	-	-	-	-	-	-
ECOG-ACRIN	7	-	7	-	-	-	-	-	-	-
NRG	2	-	1	-	-	-	-	-	-	-
Total	81	13	45	44	38	65	4	172	2	24