

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
 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: TBD

Time/Location

Saturday, October 22, 2022 9:30 am - 12:30 pm
 Room: Regency C (Ballroom Level, West Tower)

Agenda

9:30 - 9:50 am Update in CLL clinical trials - Mazyar Shadman
9:50 - 10:20 am Screening Trial for Myelomatch: Nuts and Bolts - Jerry Radich
10:20 - 10:50 am Myelomatch: Science - Cecilia Yeung
10:50 - 11:10 am Cytogenetics and Myelomatch - Min Fang
11:10 - 11:40 am Myelomatch: Clinical Trials - Laura Michaelis
11:40 - 12:00 pm How do sites open studies in Myelomatch, Beacon Builds, NCORP Sites - Harry Erba and group
12:00 - 12:20 pm CML - Current and Upcoming Trials - Jerry Radich

AML/MDS Studies

Active Studies

CTSUA041701, "A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy." Dr. L. Liesveld. Activated: 1/16/19.

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. L. Michaelis, R. Walter, S. Assouline, et al. Activated: 12/22/17; Closed: 9/1/20.

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

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.

S1612, "A Randomized Phase II/III Trial of "Novel Therapeutic(s)" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia Age 60 or Older." Drs. Michaelis and Walter. Activated: 12/22/17; Closed: 10/22/18.

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. A. Advani, N. Papadantonakis, and C. Yeung. Activated: 8/17/20.

CTSUA041501, "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. A. Advani. Activated: 6/1/17.

Proposed Studies

S2113, "A Randomized Phase II Trial to Evaluate the Efficacy of Combination Bcl-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy

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Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma." Dr. K. O'Dwyer.

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: 11/01/09.

S1312, "A Phase I Study of Inotuzumab Ozogamicin in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia, and Burkitt's Leukemia)." Drs. A. 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. A. Advani and K. 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. D. Stephens, B. Hill, J. Pagel, et al. Activated: 12/14/20.

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. B. Hill. Activation: 1/4/19.

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. M. Shadman. Activated: 1/3/19. Closed: 4/30/21.

CML Studies

Active 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. K. Sweet and J. Radich. Activated: 7/20/18.

MyeloMATCH

Proposed Studies

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

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

MM1OA-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. R. Shallis, D. Sallman, and A. Zeidan.

Proposed Studies (Pre-Triage)

MM1XX-S##, "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. U. Borate and E. Huselton.

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Accrual from trial opening through 6/30/2022 by Institution and Study

	S1318	S1712	S1905	S1925	A041501	A041701	A041702	A041703	EA9161	EA9171	EA9181
Ascension Via Christi Hospitals Wichita	1	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	-	-	-	-	-	5	-	4	-	-
Baptist Mem HC/Mid South MU NCORP	-	1	-	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	6	-	1	2	4	-	5	-	-	-	-
Ca Res for the Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
City of Hope CCC	4	-	2	1	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	-	-	-	-	-	-	-	-	1	-	-
Dayton NCORP	-	-	-	-	-	-	1	-	2	-	-
Duke U - Duke Ca Inst LAPS	-	3	-	-	-	-	-	-	9	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	1	2	-	-	-	-	-	9	-	-
Hawaii MU NCORP	-	6	-	-	-	-	-	-	-	-	1
Heartland Ca Res NCORP	1	4	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	2	-	4	3	-	1	-	-
Intermountain Med Ctr	-	-	-	-	2	-	-	-	-	-	-
Kaiser Permanente NCORP	-	-	-	-	-	-	7	-	32	-	-
Lahey Hospital & Med Ctr	-	-	-	-	-	-	1	-	-	-	-
Loma Linda U Med Ctr	1	-	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	1	-	-	-	-	1	-	2	-	1
Medical U of South Carolina MU NCORP	-	-	-	1	-	-	1	-	7	-	-
Michigan Ca Res Consortium NCORP	-	1	-	4	-	-	1	-	-	-	-
Moffitt CC	-	16	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	1	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hth NCORP)	1	1	-	-	-	-	-	-	1	-	-
Nevada Ca Res Foundation NCORP	-	2	-	-	-	-	3	-	5	-	-
New Mexico MU NCORP	1	3	-	-	-	-	-	-	1	-	-

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	S1318	S1712	S1905	S1925	A041501	A041701	A041702	A041703	EA9161	EA9171	EA9181
Northwell Health NCORP	-	-	-	-	-	2	-	-	-	-	-
Northwestern U LAPS	-	-	-	-	3	1	2	-	-	-	3
Oregon Health & Science U	-	3	1	-	8	-	5	-	9	-	-
Orlando Health Ca Inst	1	-	-	-	-	-	-	-	-	-	-
Salem Hospital	-	-	-	-	-	-	-	-	4	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	2	-	-
Stanford Ca Inst Palo Alto	-	-	-	-	8	-	11	-	29	-	-
UC Davis CCC LAPS	-	-	-	1	2	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	4	-	-	-	3	-	-	-	-	-	3
UC San Diego Moores CC	1	-	-	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	3	-	-	-	-	-	-	-	-	-	-
U Alabama Birm/Deep South RC LAPS	1	-	-	-	1	-	-	-	7	-	-
U Arkansas for Medical Sciences	-	-	-	-	-	4	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	1	-	-	-	-	1	-	-	1
U Colorado CC LAPS	-	-	-	-	-	-	1	-	1	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	-	6	-	8	-	-
U Michigan CCC LAPS	2	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	4	6	1	3	7	27	1	3	1	-	5
U Utah - Huntsman Ca Inst LAPS	-	7	-	5	1	-	5	-	22	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	-	4	-	2
Western States Ca Res NCORP	-	-	-	-	-	-	2	-	1	-	-
Yale U - Yale CC LAPS	1	-	-	-	5	-	3	-	10	2	-
ALLIANCE	17	11	2	4	-	-	-	-	-	-	-
ECOG-ACRIN	6	6	-	4	-	-	-	-	-	-	-
NRG	2	2	-	-	-	-	-	-	-	-	-
Total	57	76	10	27	44	38	64	4	172	2	16