

SPRING GROUP MEETING

Seattle

Leukemia Committee

APRIL 3-6, 2024 | SEATTLE, WASHINGTON

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
 Veterans Affairs: Tsewang Tashi, MD
 Data Coordinators: Louise Highleyman, BA
 Matt Gospe, BS
 Oncology Research Professionals:
 CRA: Heather A. Thulean, BS
 Nurse: Natalie C. Sikes, MSN, RN
 Patient Advocate: Gail Sperling, MPH
 Pharmaceutical Science: Holly O. Chan, PharmD
 Ila M. Saunders, PharmD
 Sr. Protocol Project Manager: Sharon Palmer
 Sr. Protocol Project Manager - MyeloMATCH: Sarah Cantu
 Clinical Trials Program Manager: Mariah Norman, MS

Time/Location

Thursday, April 4, 2024 8:00 a.m. - 10:00 a.m.
 Room: Virtual Only

Agenda

1. Myelomatch—Harry Erba, Jerry Radich (60 minutes)
2. Update on Recent CML Trial and Where Should We Go
Kendra Sweet (30 minutes)
3. Updates in ALL Including Upcoming CTP Trial
Kristen O'Dwyer (30 minutes)

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. L. Liesveld. Activated: 1/16/19. Temporarily closed to accrual 11/19/2021

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: 9/3/20.

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; 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: 03/29/22.

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. A. Advani, N. Papadantonakis, and C. 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. A. Advani. Activated: 6/1/17. Temporarily closed to accrual: 05/24/22.

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. K. O'Dwyer, I. Aldoss, A. Advani, and W. 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. I. Aldoss, A. Advani, W. Stock, and C. Saygin.

Leukemia Committee

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.

Developing Studies

S2421, "A Randomized Phase II Study of Pirtobrutinib Plus R-CHOP vs. R-CHOP for Patients with Previously Untreated Richter Transformation (RT)." Drs. M. Shadman, D. Stephens, and A. Danilov.

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.

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: 01/04/19.

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. K. Sweet and J. Radich. Activated: 7/20/18. Closed: 10/20/22.

MyeloMATCH

Proposed Studies

MYELOMATCH, "Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI MyeloMATCH Clinical Trials." Drs. J. Radich and S. Jiwani.

MM1YA-S01, "A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs. (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome + Venetoclax in Patients Aged 59 or Younger who are Considered High-Risk (Adverse) Acute Myeloid Leukemia as Determined by myeloMATCH; A myeloMATCH Clinical Trial." Drs. P. Shami and T. Lin.

MM10A-S02, "A Phase II 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.

MM10A-S03, "A Randomized Phase II 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.

Leukemia Committee

Publications

The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Fall 2023 Group Meeting. Conference abstracts are not included.

Because of journal embargo policies, journal names are omitted for submitted or accepted manuscripts.

Published/Accepted Manuscripts

S1203 Standard versus high-dose cytarabine with or without vorinostat for AML. Garcia-Manero G, Podoltsev N, Othus M, Pagel J, Radich J, Fang M, Rizzieri D, Marcucci G, Strickland SA, Litzow MR, Savoie M, Medeiros B, Sekeres M, Lin TL, Uy G, Powell BL, Kolitz JE, Larson RA, Stone RM, Claxton D, Essell J, Luger S, Mohan S, Moseley A, Appelbaum F, Erba HP. *Leukemia* Jan;38(1):58-66, 2024. <https://pubmed.ncbi.nlm.nih.gov/37935977/>

Multiple Studies Clinical Evaluation of Complete Remission (CR) with Partial Hematologic Recovery (CRh) in Acute Myeloid Leukemia: A Report of 7,235 Patients from Seven Cohorts. Appelbaum J, Wei A, Mandrekar S, Tiong I, Chua C, Teh T, Fong C, Ting S, Weber D, Benner A, Hill H, Saadati M, Yin J, Stone R, Garcia-Manero G, Erba H, Yy G, Marcucci G, Larson R, Thomas A, Freeman S, Marquez Almuina N, Dohner K, Thomas I, Russel N, Dohner H, Othus M, Estey E, Walter R. *Leukemia* Feb;38(2):389-392,2024. <https://pubmed.ncbi.nlm.nih.gov/38263433/>

A041202 Long Term Follow-up from A041202, A Phase 3 Study of Bendamustine/Rituximab vs Ibrutinib or Ibrutinib/Rituximab Shows Continued Efficacy and Safety of Ibrutinib in Older Adults with CLL Woyach J, Burbano G, Ruppert A, Miller C, Heerema N, Zhao W, Wall A, Ding W, Bartlett N, Brander D, Barr P, Rogers K, Parekh S, Stephens D, Brown J, Lozanski G, Blachly J, Nattam S, Larson R, Erba H, Litzow M, Luger S, Owen C, Kuzma C, Abramson J, Little R, Dinner S, Stone R, Uy G, Stock W, Mandrekar S, Byrd J. *Blood* Jan 12: blood.2023021959. doi: 10.1182/blood.2023021959. Online ahead of print, 2024. <https://pubmed.ncbi.nlm.nih.gov/38215395/>

Submitted Manuscripts

None this cycle

Leukemia Committee

Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	S1712	S1905	S1925	A041501	A041701	A041702	A041703	A042001	EA9152	EA9171	EA9181	EA9213
Banner University Medical Center - Tucson	-	-	-	-	-	5	-	-	-	-	-	-
Baptist Mem Health Care/Mid South MU-NCORP	1	-	-	-	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	1	6	4	-	5	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	-	1	-	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	3	1	-	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	1	-	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS	3	-	1	-	-	-	-	-	-	-	1	-
Fred Hutchinson Cancer Research Center LAPS	1	4	1	-	-	-	-	-	-	-	-	3
Hawaii Minority Underserved NCORP	6	-	-	-	-	-	-	-	-	-	3	-
Heartland Cancer Research NCORP	5	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	2	-	4	3	-	-	-	-	-	-
Intermountain Medical Center	-	-	-	2	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	-	-	-	-	-	8	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	1	-	-	-	-	-	-
Loyola University Medical Center	1	-	1	-	-	1	-	-	-	-	1	-
Medical U of S Carolina Minority Underserved NCORP	-	-	3	-	-	1	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	1	-	5	-	-	1	-	-	-	-	-	-
Moffitt Cancer Center	16	-	-	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	1	-	-	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	1	-	-	-	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	2	-	-	-	-	3	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	3	-	-	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	2	-	-	-	-	-	-	-
Northwestern University LAPS	-	-	-	3	1	2	-	1	-	-	4	-
Oregon Health and Science University	3	1	-	8	-	5	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	1	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	1	-	-	-	-	-	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	8	-	11	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	2	2	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	3	-	-	1	-	-	-	9	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-	-	-	1	-
U of Alabama at Birm/Deep South Res Consort LAPS	-	-	-	1	-	-	-	1	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	4	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	2	-	-	-	-	1	-	-	-	1	-
University of Colorado Cancer Center LAPS	-	-	-	-	-	1	-	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	6	-	-	-	-	-	-
University of Rochester LAPS	7	1	7	7	27	1	3	-	-	-	6	-
University of Utah - Huntsman Cancer Institute LAPS	7	-	15	1	-	5	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	-	3	-
Western States Cancer Research NCORP	-	-	-	-	-	2	-	-	-	1	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	5	-	3	-	-	2	2	1	-
ALLIANCE	13	2	17	-	-	-	-	-	-	-	-	-
CCTG	-	-	6	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	7	-	11	-	-	-	-	-	-	-	-	-
NRG	2	-	3	-	-	-	-	-	-	-	-	-
Total	81	14	85	44	38	65	5	2	2	3	30	3

