

# 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, 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  
 Protocol Project Manager: ..... Sharon Palmer  
 Protocol Project Manager - MyeloMATCH: ..... Sarah Cantu  
 Clinical Trials Program Manager: ..... Mariah Norman, MS

## Time/Location

Friday, October 13, 2023 4:30 p.m. - 6:30 p.m.  
 Room: Regency C (Ballroom Level, West Tower)

## Agenda

### AML/MDS Studies

#### Active Studies

**CTS/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. Temporarily closed to accrual: 12/23/22.

**CTS/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.

### 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.

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**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.

### 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.

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## Accrual from trial opening through 6/30/2023 by Institution and Study

	S1712	S1905	S1925	A041501	A041701	A041702	A041703	EA9152	EA9171	EA9181	EA9213
Banner University Medical Center – Tucson	-	-	-	-	-	5	-	-	-	-	-
Baptist Mem Hlth Care/Mid South MU-NCORP	1	-	-	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	1	5	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	3	1	-	-	-	-	-	-	-	1
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	-
Med Univ of South Carolina MU-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	-	-	-	4	-
Oregon Health and Science University	3	1	-	8	-	5	-	-	-	-	-
STCC at DHR Hlth Inst for Res & Dev	-	-	1	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	1	-	-	-	-	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	8	-	11	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	2	2	-	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	3	-	-	-	-	-	8	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-	-	1	-
U of Alabama at Birm/Deep South Res Consort LAPS	-	-	-	1	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	4	-	-	-	-	-	-
U of Cincinnati CC-UC Med Ctr	-	2	-	-	-	-	1	-	-	1	-
University of Colorado Cancer Center LAPS	-	-	-	-	-	1	-	-	-	-	-
U of Kansas CC-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	-	12	1	-	5	-	-	-	-	-
Wayne State Univ-Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	-	-	3	-
Western States Cancer Research NCORP	-	-	-	-	-	2	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	5	-	3	-	1	2	1	-
ALLIANCE	13	2	15	-	-	-	-	-	-	-	-
CCTG	-	-	3	-	-	-	-	-	-	-	-
ECOG-ACRIN	7	-	9	-	-	-	-	-	-	-	-
NRG	2	-	2	-	-	-	-	-	-	-	-
<b>Total</b>	<b>81</b>	<b>13</b>	<b>72</b>	<b>44</b>	<b>38</b>	<b>65</b>	<b>4</b>	<b>1</b>	<b>2</b>	<b>29</b>	<b>1</b>