

# 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  
..... Tracy Maher, CCRP  
..... Laura Kingsbury  
Oncology Research Professionals:  
CRA: ..... TBD  
Nurse: ..... Kristine D. Abueg, RN, MSN  
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, April 9, 2022 8:15 - 10:15 am  
VIRTUAL ONLY

## 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. 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.

**S1318**, "A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory 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, O'Dwyer, and Wood. Activated: 1/12/15; Permanent Closure of Cohort 1: 9/15/17; Permanent Closure of Steps 1 and 2: 4/15/21.

**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.

### Proposed Studies

**S2113**, "A Randomized Phase II Trial to Evaluate the Efficacy of Combination Bcl-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma." Dr. K. O'Dwyer.

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## 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." Dr. P. Shami.

**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." Dr. R. Shallis.

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Accrual from trial opening through 12/31/2021 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	-	-	-	-	-	-	4	-	4	-	-
Baptist Mem HC/Mid South MU NCORP	-	1	-	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	6	-	1	1	4	-	3	-	-	-	-
Ca Res for the Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
City of Hope CCC	4	-	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	1	-	-	-	-	-	9	-	-
Hawaii MU NCORP	-	6	-	-	-	-	-	-	-	-	1
Heartland Ca Res NCORP	1	4	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	1	-	4	3	-	1	-	-
Intermountain Med Ctr	-	-	-	-	2	-	-	-	-	-	-
Kaiser Permanente NCORP	-	-	-	-	-	-	6	-	32	-	-
Lahey Hospital & Med Ctr	-	-	-	-	-	-	1	-	-	-	-
Loma Linda U Med Ctr	1	-	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	1	-	-	-	-	1	-	2	-	-
Medical U South Carolina MU NCORP	-	-	-	1	-	-	1	-	7	-	-
Michigan Ca Res Consortium NCORP	-	1	-	1	-	-	-	-	-	-	-
Moffitt CC	-	11	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	1	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	1	1	-	-	-	-	-	-	1	-	-
Nevada Ca Res Foundation NCORP	-	1	-	-	-	-	3	-	5	-	-
New Mexico MU NCORP	1	3	-	-	-	-	-	-	1	-	-
Northwell Health NCORP	-	-	-	-	-	2	-	-	-	-	-

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	S1318	S1712	S1905	S1925	A041501	A041701	A041702	A041703	EA9161	EA9171	EA9181
Northwestern U LAPS	-	-	-	-	1	1	2	-	-	-	3
Oregon Health & Science U	-	3	1	-	7	-	4	-	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	-	-	-	-	2	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	4	-	-	-	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	5	1	2	5	27	1	3	1	-	5
U Utah - Huntsman Ca Inst LAPS	-	5	-	4	1	-	4	-	22	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	-	4	-	2
Western States Ca Res NCORP	-	-	-	-	-	-	2	-	1	-	-
Yale U - Yale CC LAPS	1	-	-	-	4	-	2	-	10	2	-
ALLIANCE	17	9	2	1	-	-	-	-	-	-	-
ECOG-ACRIN	6	5	-	2	-	-	-	-	-	-	-
NRG	2	2	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>57</b>	<b>64</b>	<b>8</b>	<b>13</b>	<b>38</b>	<b>38</b>	<b>56</b>	<b>4</b>	<b>172</b>	<b>2</b>	<b>12</b>