

Barlogie-Salmon Myeloma Committee

Leadership

Chair: Robert Z. Orlowski, MD, PhD
 Vice-Chair: Sikander Ailawadhi, MD
 Vice-Chair: Jing Christine Ye, MD, MSc
 Executive Officer: Susan M. O'Brien, MD
 Statisticians: Antje Hoering, PhD
 Rachael Sexton, MS
 Adam Rosenthal

Scientific Leadership

Translational Medicine: Brian A. Walker, BSc, PhD
 Radiation: Chelsea Camille Pinnix, MD, PhD
 Surgery: TBD
 Imaging: Eric M. Rohren, MD, PhD
 Pathology: Pei Lin, MD
 Early Therapeutics: Frits van Rhee, MD, PhD

Designates

DEI Champion: Manuel Espinoza-Gutarra, MD
 Digital Engagement: TBD
 NCORP Representative: Charles S. Kuzma, MD
 Veterans Affairs: Thomas R. Chauncey, MD, PhD
 Data Coordinators: Daria Chugina
 Hannah Hale
 Oncology Research Professionals:
 CRA: Brandon Richard Labadie, CCRP
 Nurses: Teresa Witcher, BSN, RN
 Patient Advocate: Jack Aiello, MS
 Pharmaceutical Science: Craig Elg, PharmD
 Ila M. Saunders, PharmD
 Protocol Project Manager: Sharon Palmer
 Clinical Trials Program Manager: Mariah Norman, MS

Time/Location

Friday, May 12, 2023 7:30 am - 9:30 am
 Room: Pacific JK (Pacific Concourse Level)

Agenda

Active Studies

- S1803**, "Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. Krishnan and Hari. Activated: 6/27/19.
- S2005**, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previously Untreated Waldenström's

Macroglobulinemia (WM)." Drs. Ailawadhi and Bhutani. Activated: 6/24/21. Temporarily Closed: 7/16/21. Re-opened to accrual: 10/15/21. Temporary Closed: 4/8/22.

EAA171, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. Kumar. Activated: 6/1/21.

EAA173, "Lenalidomide, and Dexamethasone With or Without Daratumumab in Treating Patients With High-Risk Smoldering Myeloma." Activated: 4/30/19.

EAA181, "Testing the Use of Combination Therapy in Adult Patients With Newly Diagnosed Multiple Myeloma, the EQUATE Trial." Activated: 10/27/20.

Closed Studies

S1211, "A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or Without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)." Drs. Usmani, Ailawadhi, and Lipe. Activated: 11/9/12. Closed: 6/2/16.

S1702, "A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis." Drs. Parker and Sanchorawala. Activated: 3/8/18; Closed: 9/30/19.

S1304, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib with Dexamethasone for Relapse/Refractory Multiple Myeloma." Dr. Ailawadhi. Activated: 10/18/13. Closed: 11/6/15.

S0777, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. Durie. Activated: 4/1/18. Closed: 2/2/12.

S0120, "A prospective Observational Biologic Study of Asymptomatic Patients with Monoclonal Gammopathy and Plasmaproliferative Disorders." Dr. Dhodapkar. Activated: 6/1/02. Closed: 4/1/11.

CTN 0702, "Single Autologous Transplant with or without RVD Consolidation versus Tandem Transplant and Maintenance Therapy." Dr. Somlo. Activated: 2/15/11. Closed: 11/15/13.

A061402, "Ixazomib Citrate, Lenalidomide, Dexamethasone, and Zoledronic Acid or Zoledronic Acid Alone after Radiation Therapy in Treating Patients with Solitary Plasmacytoma of Bone." Dr. Kuman Mahindra. Activated: 12/23/15. Closed: 8/15/19.

E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite Duration

Barlogie-Salmon Myeloma Committee

Lenalidomide Maintenance in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE).” Drs. Kumar, Cohen, and Zonder. Activated: 11/22/13. Closed: 1/29/19.

E3A06 (was S0909), “High-risk AMM – Revlimid.” Dr. Dhodopkar. Activated: 1/17/11. Closed: 7/14/17.

A061402, “Ixazomib Citrate, Lenalidomide, Dexamethasone, and Zoledronic Acid or Zoledronic Acid Alone after Radiation Therapy in Treating Patients with Solitary Plasmacytoma of Bone.” Dr. Kumar Mahindra. Activated: 12/23/15. Closed: 8/15/19.

E1A11, “Randomized Phase III Trial of Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE).” Drs. Kumar, Cohen and Zonder. Activated: 11/22/13. Closed: 1/29/19.

Developing Studies

S2209, “A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd).” Drs. Ailawadhi, Ye, Lipe, Chauncey, and Gowin.

S2213, “Daratumumab, Cyclophosphamide, Bortezomib, and Dexamethasone (D-VCD) Induction Followed by Autologous Stem Cell Transplant or D-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis.” Drs. Hagen, Parker, and Sidana.

Proposed Studies

Sxxx, “Phase III Study of Optimal Induction Therapy for Newly Diagnosed High-Risk Multiple Myeloma (HRMM) RVd Dara +/- xx.” Dr. Lipe.

Proposed Studies-Pre-Triage/On Hold

1. Bhutani: Randomized Phase II of CAEL-101 vs Placebo in Renal AL Amyloidosis. Amyloid two-arm study.
2. Gowin: PCL Phase II study of VTD-PACE like regimen/Belanatumab Mafodotin/Autologous menStem Cell Transplant (ASCT).
3. Atrash: PVD +/- Sel in RRMM with del(17p) and prior therapy.
4. Former S1710 (Now VTE substudy proposal for S2209): Randomized Phase II Trial of Apixaban (or Riveroxiban) for Prevention of Thromboembolism in High Risk Patients being Treated with IMiDs for Multiple Myeloma (MM)- David Calverly
5. Chakraborty: An Open-Label Randomized Phase 2 Trial to Incorporate Venetoclax in Early Relapsed t(11;14) Multiple Myeloma

Barlogie-Salmon Myeloma Committee

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

	S1803	S2005	EAA173	EAA181
Ascension Providence Hospitals - Southfield	1	-	1	-
Banner University Medical Center - Tucson	7	-	-	1
Boston Medical Center	5	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	16	-	3	-
Cancer Research for the Ozarks NCORP	1	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	4	-	-	-
Cedars-Sinai Medical Center	6	-	-	-
City of Hope Comprehensive Cancer Center	93	-	-	-
Columbus NCI Community Oncology Research Program	8	-	-	-
CommonSpirit Health Research Institute	3	-	-	-
Dayton NCI Community Oncology Research Program	5	-	-	-
Duke University - Duke Cancer Institute LAPS	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	5	-
Froedtert and the Medical College of Wisconsin LAPS	2	-	-	-
Georgia NCI Community Oncology Research Program	13	-	-	-
Gulf South Minority Underserved NCORP	4	-	-	-
Heartland Cancer Research NCORP	14	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	37	-	-	-
Lahey Hospital and Medical Center	3	-	-	-
Loyola University Medical Center	19	-	3	-
Medical University of South Carolina Minority Underserved NCORP	35	-	1	-
Michigan Cancer Research Consortium NCORP	2	-	-	-
Moffitt Cancer Center	39	-	-	-
Montana Cancer Consortium NCORP	4	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	1	-
New Mexico Minority Underserved NCORP	10	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	4	-	-	-
Oregon Health and Science University	22	-	2	7
Pacific Cancer Research Consortium NCORP	13	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	-	-	-
UC Davis Comprehensive Cancer Center LAPS	18	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	10	-	-	-
University of Arkansas for Medical Sciences	-	-	-	2
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	1
University of Kansas Cancer Center - MCA Rural MU NCORP	27	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	10	-	-	-
University of Oklahoma Health Sciences Center LAPS	2	-	-	-
University of Rochester LAPS	14	-	-	-
University of Texas Health Science Center at San Antonio	12	-	-	-
University of Texas MD Anderson Cancer Center LAPS	23	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	14	-	3	1
Upstate Carolina Consortium Community Oncology Research Program	4	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	12	-	-	-
Wisconsin NCI Community Oncology Research Program	18	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	2	1
ALLIANCE	162	-	-	-
CCTG	1	-	-	-
ECOG-ACRIN	141	1	-	-
NRG	81	-	-	-
Total	925	1	21	13