

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, MS

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: Aubrey Gilmore, BA
 Daria Chugina, MD, CCRPS
 Pasarlai Ahmadzai, MD, MPH
 Oncology Research Professionals:
 CRA: Brandon Richard Labadie, CCRP
 Nurse: 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, October 13, 2023 2:30 p.m. - 4:30 p.m.

Room: Crystal A (Lobby Level, West Tower)

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. A. Krishnan and P. Hari. Activated: 6/27/19. Temporarily closed to accrual 03/29/23.

S2005, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previously Untreated Waldenström's Macroglobulinemia (WM)." Drs. S. Ailawadhi and D. Bhutani. Activated: 6/24/21. Temporarily Closed: 7/16/21. Re-opened to accrual: 10/15/21. Temporarily closed to accrual 04/08/22.

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. S. Ailawadhi, J.C. Ye, B. Lipe, T. Chauncey, and K. Gowin. Activated 05/30/23.

EAA171, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. S. Kumar. Activated: 6/1/21. Closed 03/03/23.

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. S. Usmani, S. Ailawadhi, and B. 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. T. Parker and V. Santhorawala. Activated: 3/08/18; Closed: 9/30/19.

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

S0777, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. B. Durie. Activated: 4/1/08. Closed: 2/2/12.

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

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

	S1803	S2005	EAA173	EAA181
Ascension Providence Hospitals - Southfield	1	-	1	-
Banner University Medical Center - Tucson	8	-	-	1
Boston Medical Center	5	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	23	-	3	-
Cancer Research for the Ozarks NCORP	2	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	4	-	-	-
Cedars-Sinai Medical Center	6	-	-	-
City of Hope Comprehensive Cancer Center	98	-	-	-
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	7	-	-	-
Georgia NCI Community Oncology Research Program	13	-	-	-
Gulf South Minority Underserved NCORP	4	-	-	-
Heartland Cancer Research NCORP	14	-	-	-
Houston Methodist Hospital	4	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	40	-	-	-
Lahey Hospital and Medical Center	3	-	-	-
Loyola University Medical Center	22	-	3	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	-	2
Medical University of South Carolina Minority Underserved NCORP	43	-	1	1
Mercy Medical Center - Des Moines	1	-	-	-
Michigan Cancer Research Consortium NCORP	7	-	-	-
Moffitt Cancer Center	41	-	-	-
Montana Cancer Consortium NCORP	4	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	1	-
New Mexico Minority Underserved NCORP	11	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	4	-	-	-
Oregon Health and Science University	25	-	3	8
Pacific Cancer Research Consortium NCORP	15	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	-	-	-
UC Davis Comprehensive Cancer Center LAPS	20	-	-	-
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	30	-	-	-
University of Kentucky/Markey Cancer Center	3	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	13	-	-	-
University of Oklahoma Health Sciences Center LAPS	2	-	-	-
University of Rochester LAPS	15	-	-	-
University of Texas Health Science Center at San Antonio	14	-	-	-
University of Texas MD Anderson Cancer Center LAPS	24	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	16	-	3	1
Upstate Carolina Consortium Community Oncology Research Program	4	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	13	-	-	-
Wisconsin NCI Community Oncology Research Program	18	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	3	4
ALLIANCE	181	-	-	-
CCTG	6	-	-	-
ECOG-ACRIN	153	1	-	-
NRG	87	-	-	-
Total	1,036	1	23	20

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CTN 0702, "Single Autologous Transplant with or without RVD Consolidation versus Tandem Transplant and Maintenance Therapy." Dr. G. 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. A. 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 Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Drs. S. Kumar, A. Cohen, and J. Zonder. Activated: 11/22/13. Closed: 1/29/19.

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

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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. S. Kumar, A. Cohen and J. Zonder. Activated: 11/22/13. Closed: 1/29/19.

Developing Studies

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. P. Hagen, T. Parker, and S. Sidana.

Proposed Studies- At Triage

Sxxxx, "Phase III Study of Optimal Induction and MRD Driven Maintenance Therapy for Newly Diagnosed High-Risk Multiple Myeloma (HRMM)." Drs. B. Lipe, J.C. Ye, and K. Gowin.

Proposed Studies-Pre-Triage/On Hold

1. **Sxxxx**: "An Open-Label Randomized Phase 2 Trial to Incorporate Venetoclax in Early Relapsed t(11;14) Multiple Myeloma." Dr. R. Chakraborty.
2. **Sxxxx**: "CAEL-101 in Real AL Amyloidosis". Dr. D. Bhutani
3. **Sxxxx**: Developing Smoldering Multiple Myeloma Concept. Dr. P. Hagen