

# 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: ..... TBD  
 Nurses: ..... Deborah A. Shaw, RN  
 ..... 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: ..... TBD

## Time/Location

Friday, October 21, 2022 2:30 pm - 4:30 pm  
 Room: Plaza B (Lobby Level, East Tower)

## 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.

**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. Temporary Closed: 4/08/22.

**EAA171**, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. S. 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. 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. Sanchorawala. 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.

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**S0777**, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. B. 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. M. 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. 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 (ENDUR-ANCE)." 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.

**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. Kumar Mahindra. Activated: 12/23/15. Closed: 8/15/19.

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## Proposed 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. S. Ailawadhi, C. Ye, and A. 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." Dr. P. Hagen

**S1911**, "Phase III Study of Optimal Induction Therapy for Newly Diagnosed High-Risk Multiple Myeloma (HRMM) RVD Dara +/- xx." Dr. B. 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 6/30/2022 by Institution and Study

	S1803	S2005	EAA173	EAA181
<i>Ascension Providence Hospitals - Southfield</i>	1	-	-	-
<i>Banner University Medical Center - Tucson</i>	6	-	-	-
<i>Boston Medical Center</i>	5	-	-	-
<i>CWRU Case Comprehensive Cancer Center LAPS</i>	15	-	3	-
<i>Cancer Research for the Ozarks NCORP</i>	1	-	-	-
<i>Cancer Research of Wisconsin and Northern Michigan Consortium</i>	3	-	-	-
<i>Cedars-Sinai Medical Center</i>	5	-	-	-
<i>City of Hope Comprehensive Cancer Center</i>	78	-	-	-
<i>Columbus NCI Community Oncology Research Program</i>	7	-	-	-
<i>CommonSpirit Health Research Institute</i>	3	-	-	-
<i>Dayton NCI Community Oncology Research Program</i>	5	-	-	-
<i>Duke University - Duke Cancer Institute LAPS</i>	3	-	-	-
<i>Fred Hutchinson Cancer Research Center LAPS</i>	-	-	4	-
<i>Georgia NCI Community Oncology Research Program</i>	11	-	-	-
<i>Gulf South Minority Underserved NCORP</i>	4	-	-	-
<i>Heartland Cancer Research NCORP</i>	14	-	-	-
<i>Kaiser Permanente NCI Community Oncology Research Program</i>	37	-	-	-
<i>Lahey Hospital and Medical Center</i>	3	-	-	-
<i>Loyola University Medical Center</i>	19	-	3	-
<i>Medical University of South Carolina Minority Underserved NCORP</i>	29	-	1	-
<i>Moffitt Cancer Center</i>	36	-	-	-
<i>Montana Cancer Consortium NCORP</i>	4	-	-	-
<i>Nevada Cancer Research Foundation NCORP</i>	-	-	1	-

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Accrual from trial opening through 6/30/2022 by Institution and Study

	S1803	S2005	EAA173	EAA181
<i>New Mexico Minority Underserved NCORP</i>	8	-	-	-
<i>Ohio State University Comprehensive Cancer Center LAPS</i>	4	-	-	-
<i>Oregon Health and Science University</i>	17	-	2	3
<i>Pacific Cancer Research Consortium NCORP</i>	10	-	-	-
<i>Southeast Clinical Oncology Research Consortium NCORP</i>	3	-	-	-
<i>UC Davis Comprehensive Cancer Center LAPS</i>	17	-	-	-
<i>UC Irvine Health/Chao Family Comprehensive Cancer Center</i>	7	-	-	-
<i>University of Arkansas for Medical Sciences</i>	-	-	-	1
<i>University of Cincinnati Cancer Center-UC Medical Center</i>	-	-	-	1
<i>University of Kansas Cancer Center - MCA Rural MU NCORP</i>	23	-	-	-
<i>University of Michigan Comprehensive Cancer Center LAPS</i>	9	-	-	-
<i>University of Oklahoma Health Sciences Center LAPS</i>	2	-	-	-
<i>University of Rochester LAPS</i>	12	-	-	-
<i>University of Texas Health Science Center at San Antonio</i>	12	-	-	-
<i>University of Texas MD Anderson Cancer Center LAPS</i>	19	-	-	-
<i>University of Utah - Huntsman Cancer Institute LAPS</i>	12	-	3	1
<i>Upstate Carolina Consortium Community Oncology Research Program</i>	3	-	-	-
<i>Wayne State University - Karmanos Cancer Institute LAPS</i>	10	-	-	-
<i>Wisconsin NCI Community Oncology Research Program</i>	16	-	-	-
<i>Yale University - Yale Cancer Center LAPS</i>	-	-	2	1
<b>ALLIANCE</b>	139	-	-	-
<b>ECOG-ACRIN</b>	117	1	-	-
<b>NRG</b>	72	-	-	-
<b>Total</b>	<b>801</b>	<b>1</b>	<b>19</b>	<b>7</b>