

Melanoma Committee

Leadership

Chair: Sapna P. Patel, MD
 Vice-Chair: Roger S. Lo, MD, PhD
 Executive Officer: Christopher W. Ryan, MD
 Statisticians: Michael Wu, PhD
 Megan Othus, PhD
 James Moon, MS
 Hongli Li, MS
 Gabby Lopez

Scientific Leadership

Translational Medicine: William E. Carson, III, MD
 Radiation Oncology: Evan J. Wuthrick, MD
 Surgery: John Robert Hyingstrom, MD
 Dermatology: Clara Curiel-Lewandrowski, MD
 Imaging: Ari M. VanderWalde, MD
 Medical Oncology: Sapna Pradyuman Patel, MD
 Pathology: TBD
 Non-Melanoma Skin Cancer: Nikhil I. Khushalani, MD
 Early Therapeutics: Jeffrey A. Sosman, MD
 SWOG's ECOG Liaisons: Thach-Giao Truong, MD
 ECOG's SWOG Liaisons: David H. Lawson, MD
 Andrew Poklepovic, MD
 Digital Engagement: Zeynep Eroglu, MD

Designates

Cancer Control Liaison: Sancy Leachman, MD, PhD
 Thach-Giao Truong, MD (Survivorship)
 Data Coordinator: Laura Kingsbury, MRT
 Leah Everhart
 Hannah Hale
 Oncology Research Professionals:
 CRA: Kathryn Allen, BA, CCRP
 Nurse: Lisa S. Morgan, RN, OCN
 Patient Advocate: Samantha Guild, J.D.
 Pharmaceutical Science: Sun "Coco" Yang, PharmD, PhD
 Kimberly McConnell, PharmD
 Protocol Project Manager: Catrina De Los Santos-Mireles
 Clinical Trials Program Manager: Laura Gildner, MS

Time/Location

Friday, May 12, 2023 2:15 pm - 4:15 pm
 Room: Garden Room (Atrium Lobby Level)

Agenda

2:15 - 2:25 pm: Welcome and Introduction: Sapna Patel, MD
2:25 - 3:05 pm: Keynote Speaker: The issue with the tissue – pathological review in neoadjuvant trials
 Victor G. Prieto, MD, PhD, MD Anderson Cancer Center

3:05 - 3:20 pm Active Studies Update

S2015, Melanoma Margins Trial (MelMarT-II): A Phase III, Multi-centre, Multi-National Randomised Controlled Trial Investigating 1cm vs. 2cm Wide Excision Margins for Primary Cutaneous Melanoma
 PI: Joshua Mammen, MD, PhD (University of Nebraska)
 Biostatisticians: Michael Wu, PhD & James Moon, MS

S2000, A Randomized Phase II Trial Of Encorafenib + Binimetinib + Nivolumab Vs Ipilimumab + Nivolumab In Braf-V600 Mutant Melanoma With (Symptomatic) Brain Metastases
 PI: Zeynep Eroglu, MD (Moffit)
 Biostatisticians: Michael Wu, PhD & James Moon, MS

3:20 - 3:45 pm Closed to Patient Accrual, Manuscript & Translational Medicine Updates

S1512, A Study of PD-1 Blockade with Pembrolizumab In Patients with Primary Desmoplastic Melanoma (DM), Locally Advanced, Locally Recurrent, or Metastatic Desmoplastic Melanoma (DM)
 PI: Kari Kendra, MD (Ohio State)
 Biostatisticians: Michael Wu, PhD & James Moon, MS

S1607, A Phase II Study of Combining T-VEC and PD-1 Blockade With Pembrolizumab In Patients With Advanced Melanoma Who Have Progressed On Anti-PD1 Therapy.
 PI: Siwen Hu-Lieskovan, MD, PhD (Huntsman Cancer Institute)
 Biostatisticians: Michael Wu, PhD & James Moon, MS

S1616, A Phase II Study of Ipilimumab and Nivolumab in Advanced Melanoma Following Progression on a PD-1 Inhibitor Alone
 PI: Ari VanderWalde, MD, MPH (West Cancer Clinic, now with Caris Life Sciences)
 Biostatisticians: Michael Wu, PhD & James Moon, MS

S1801, A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High-risk Melanoma. Activated
 PI: Sapna Patel, MD (MD Anderson)
 Biostatisticians: Megan Othus, PhD & James Moon, MS

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S1404, A Phase III Randomized Study of MK3475 versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma
PI: Sapna Patel, MD (MD Anderson)
Biostatisticians: Megan Othus, PhD, James Moon, MS, & Hongli Li, MS

3:45 - 3:55 pm **ECOG-ACRIN Updates: David Lawson, MD**

3:55 - 4:05 pm **Advocacy Remarks: Samantha Guild, JD, AIM at Melanoma**

4:05 - 4:15 pm **Wrap Up and Adjourn**

Active Studies

S2015, "Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma." Dr. Mammen. Activated: 4/8/22.

S2000, "A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Brain Metastases." Dr. Eroglu. Activated: 9/23/20.

CTSU/EA6174, "STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial." SWOG Champion: Dr. Hsu. Activated: 10/1/18.

CTSU/EA6141, "Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma." SWOG Champion: Dr. K. Kim. Activated: 9/10/15.

CTSU/EA6192, "The BAMB2 (BRAF, Autophagy, MEK Inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or Without Hydroxychloroquine in Advanced BRAF V600E/K Melanoma with Elevated LDH". SWOG Champion: Dr. Truong. Activated: 10/23/20.

A091903, "A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma." SWOG Champion: Dr. Tsai (SWOG) Activated 6/1/22.

Closed Studies

S1801, "A Phase II Randomized Study of Adjuvant Versus Neoadjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High Risk Melanoma." Dr. Patel. Activated: 12/6/18. Closed: 5/5/22.

S1512, "A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan. Activated: 10/20/16. Closed: 6/4/21.

S1607, "A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and MK-3475 (Pembrolizumab) in Patients with Advanced Melanoma who have Progressed on Anti-PD1/L1 Based Therapy." Dr. Hu-Lieskovan. Activated: 10/2/17. Closed: 11/1/20.

S1616, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent." Dr. VanderWalde. Activated: 7/17/17. Closed: 7/15/20.

S1404, "A Phase III Randomized Study of MK3475 versus High-Dose Interferon a-2b for Resected High-Risk Melanoma." Dr. Patel. Activated: 10/15/15. Closed: 11/2/17.

CTSU/EA6134, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." SWOG Champion: Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/21.

CTSU/EA6183, "A Phase II Neoadjuvant Study of Encorafenib with Binimetinib in Patients with Resectable Locoregional Metastases from Cutaneous or Unknown Primary Melanoma (Stages III N1B/C/D)." SWOG Champion: Dr. Lao. Activated: 2/18/20. Closed: 9/23/22.

Studies in Development

S2305, "Phase II Study of the Triplet Combination of Relatlimab, Nivolumab, and Ipilimumab for Melanoma with Prior Progression on Immune Checkpoint Inhibitor Therapy" Drs. Naing and Patel

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

	S1801	S2000	S2015	A091903	EA6134	EA6141	EA6174	EA6192
Banner MD Anderson CC	3	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	7	-	-	-	-	-	3	-
Baptist Mem Hlth Care/Mid South MU NCORP	1	-	-	-	-	-	-	-
Boston Med Ctr	1	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	6	-	16	-
Ca Res Consort of W Mich NCORP	26	-	27	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	1	-	-	1	1	-	-
Ca Res of Wisconsin and N Mich Consort	2	-	-	-	-	-	-	-
Carle CC NCORP	1	1	-	-	-	-	-	-
City of Hope CCC	6	-	-	-	1	3	-	-
Columbus NCORP	1	-	-	-	-	-	-	-
Dayton NCORP	-	1	-	-	-	2	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	1	-
Gulf South MU NCORP	1	-	-	-	-	-	-	-
Hawaii MU NCORP	2	-	-	-	2	-	-	-
Heartland Ca Res NCORP	6	-	-	-	-	-	-	-
Kaiser Permanente NCORP	14	-	-	-	19	23	-	-
Loma Linda U Med Ctr	2	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	5	-	-	-	-	-	-	-
Med U South Carolina MU NCORP	1	-	3	-	-	-	-	-
Michigan Ca Res Consort NCORP	5	-	-	-	-	-	-	-
Moffitt CC	-	12	6	-	-	-	-	-
Montana Ca Consort NCORP	4	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	2	-	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	1	-	1	-
New Mexico MU NCORP	1	-	-	-	-	-	-	-
Northwell Hlth NCORP	7	-	-	-	-	-	-	-
Northwestern U LAPS	13	-	7	-	-	1	1	5
Ohio State U CCC LAPS	13	1	4	-	4	-	3	1

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	S1801	S2000	S2015	A091903	EA6134	EA6141	EA6174	EA6192
Pacific Ca Res Consort NCORP	3	-	-	-	-	-	-	-
SCL Hlth Saint Joseph Hosp	-	-	-	-	-	-	1	-
Sutter Ca Res Consort	-	-	-	-	2	5	1	-
Don and Sybil Harrington CC	3	-	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	3	-	-	-	-	3	8	-
UCLA / Jonsson CCC	6	-	-	-	7	-	-	-
UPMC Hillman CC LAPS	-	1	-	-	-	-	-	-
USC Norris CCC LAPS	8	-	-	1	-	-	3	-
U Alabama Birm / Deep South RC LAPS	1	-	-	-	-	-	-	-
U Arkansas for Med Sciences	-	-	2	-	3	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	2	3	-
U Colorado CC LAPS	-	-	-	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	8	-	6	-	1	-	-	-
U Kentucky/Markey CC	4	-	-	-	-	-	-	-
U Michigan CCC LAPS	15	2	-	-	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	-	-	1	-	-	-	-	-
U Rochester LAPS	4	-	-	-	2	1	1	-
U Texas HSC at San Antonio	-	-	-	-	-	1	-	-
U Texas MD Anderson CC LAPS	10	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	20	-	4	-	-	-	8	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	2	-	-	-
Western States Ca Res NCORP	-	-	-	-	-	1	-	-
Wisconsin NCORP	9	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	1	-	-	6	1	-
ALLIANCE	32	1	4	-	-	-	-	-
ECOG-ACRIN	50	4	10	-	-	-	-	-
NRG	47	1	3	-	-	-	-	-
Total	345	25	78	1	54	49	51	6