

# 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

## Scientific Leadership

Translational Medicine: ..... William E. Carson, III, MD  
Radiation Oncology: ..... Evan J. Wuthrick, MD  
Surgery: ..... John Robert Hyngstrom, 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: ..... Tonya Johnson  
..... 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, JD  
Pharmaceutical Science: ..... Sun "Coco" Yang, PharmD, PhD  
..... Kimberly McConnell, PharmD  
Protocol Project Manager: ..... Catrina De Los Santos-Mireles  
Clinical Trials Program Manager: ..... Michelle Maxim

## Time/Location

Friday, April 8, 2022 2:30 - 4:30 pm  
Room: Quinalt, Level 5

## Agenda

**Welcome and Introduction:** Sapna Patel, M.D. (10 min)

**Keynote Speaker:** The Role of the Oncology Community in Addressing Financial Hardships from Cancer Care - Veena Shankaran, M.D., Fred Hutchinson Cancer Research Center, co-director Hutchinson Institute for Cancer Outcomes Research (HICOR) (40 min)

**Active Studies Update (15 min, 5 min ea)** – Study design, eligibility criteria, endpoints, accrual to date

**S2015**, A Phase III, Multi-centre Randomised Controlled Trial Investigating 1cm vs. 2cm Wide Excision Margins for Primary Cutaneous Melanoma, MASC. PI: Joshua Mammen, M.D., Ph.D. (University of Nebraska)

**S2000**, A Randomized Phase II Trial Of Encorafenib + Binimetinib + Nivolumab Vs Ipilimumab + Nivolumab In Braf-V600 Mutant Melanoma With Brain Metastases. PI: Zeynep Eroglu, M.D. (Moffit) Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

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

## Closed to Patient Accrual (30 min), TM Updates

**S1616**, A Phase II Study of Ipilimumab and Nivolumab in Advanced Melanoma Following Progression on a PD-1 Inhibitor Alone. PI: Ari VanderWalde, M.D., M.P.H. (West Cancer Clinic). Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

**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, M.D., Ph.D. (Huntsman Cancer Institute). Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

**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, M.D. (Ohio State) and Siwen Hu-Lieskovan, M.D., Ph.D. (Huntsman Cancer Institute). Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

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

# Melanoma Committee

**S1320**, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib and Trametinib in BRAFV600E/K Mutant Melanoma. PI: Alain Algazi, M.D. (University of California San Francisco). Biostatisticians: Megan Othus, Ph.D., James Moon, M.S.

**S1221**, Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer. PI: Alain Algazi, M.D. (University of California San Francisco) and Antoni Ribas (UCLA). Biostatisticians: Megan Othus, Ph.D. & James Moon, M.S.

**ECOG / ALLIANCE Updates: David Lawson, M.D. (10 min)**

**Advocacy:** Remarks (Samantha Guild, J.D., AIM at Melanoma)

## Closing Remarks

## Active Studies

**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.

**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.

**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.

## Closed Studies

**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: 10/02/17. 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: 07/17/17. Closed: 7/15/20.

**CTSU/EA6134**, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/2021.

## Studies in Development

**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.

## Melanoma Committee

### Accrual from trial opening through 12/31/2021 by Institution and Study

	S1512	S1607	S1616	S1801	S2000
Banner University Medical Center - Tucson	-	-	-	7	-
Boston Medical Center	-	-	-	1	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	4	20	-
Cancer Research for the Ozarks NCORP	-	-	-	-	1
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	1	2	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	1	1
City of Hope Comprehensive Cancer Center	-	-	4	6	-
Columbus NCI Community Oncology Research Program	-	-	-	1	-
Dayton NCI Community Oncology Research Program	-	-	1	-	-
Georgia NCI Community Oncology Research Program	1	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	2	-
Heartland Cancer Research NCORP	-	-	-	5	-
Henry Ford Hospital	-	4	-	-	-
Intermountain Medical Center	1	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	5	13	-
Loma Linda University Medical Center	-	-	-	2	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	-	5	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	1	-
Michigan Cancer Research Consortium NCORP	-	-	-	4	-
Moffitt Cancer Center	19	-	8	-	3
Montana Cancer Consortium NCORP	-	-	1	4	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-
New Mexico Minority Underserved NCORP	-	-	2	1	-
Northwell Health NCORP	-	-	-	6	-
Northwestern University LAPS	1	-	6	13	-
Ohio State University Comprehensive Cancer Center LAPS	6	4	8	12	-
Pacific Cancer Research Consortium NCORP	-	-	-	2	-

## Melanoma Committee

### Accrual from trial opening through 12/31/2021 by Institution and Study

	S1512	S1607	S1616	S1801	S2000
SCL Health Saint Joseph Hospital	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	1	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	2	-
The West Clinic - Wolf River	-	-	7	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	3	-
UC San Diego Moores Cancer Center	-	-	2	-	-
UCLA / Jonsson Comprehensive Cancer Center	4	8	6	5	-
USC Norris Comprehensive Cancer Center LAPS	5	5	-	8	-
University of Alabama at Birmingham / Deep South Research Consortium LAPS	-	-	-	1	-
University of Arkansas for Medical Sciences	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	2	1	2	6	-
University of Kentucky/Markey Cancer Center	-	-	-	2	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	15	1
University of Rochester LAPS	-	-	5	4	-
University of Texas Health Science Center at San Antonio	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	-	-	-	10	-
University of Utah - Huntsman Cancer Institute LAPS	10	10	1	18	-
Vanderbilt University - Ingram Cancer Center LAPS	-	1	1	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	1	8	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-
ALLIANCE	1	-	9	27	1
ECOG-ACRIN	2	8	7	40	2
NRG	4	2	13	43	1
<b>Total</b>	<b>57</b>	<b>43</b>	<b>94</b>	<b>300</b>	<b>10</b>