

Early Therapeutics & Rare Cancers Committee

Leadership

Chair: Razelle Kurzrock, MD
 Vice-Chair: Young Kwang Chae, MD, MPH
 Executive Officer: Christopher W. Ryan, MD
 Statisticians: Megan Othus, PhD
 Anna B. Moseley, MS

Designates

Data Coordinator: Christine Magner
 Digital Engagement: Kanwal Raghav, MD, MBBS
 Oncology Research Professionals:
 CRAs: TBD
 Nurse: TBD
 Pharmaceutical Science: Craig Elg, PharmD
 Sun "Coco" Yang, PharmD, PhD
 Patient Advocate: Marcia K. Horn, JD
 Protocol Project Manager: Catrina De Los Santos-Mireles
 Clinical Trials Program Manager: Laura Gildner, MS

Early Therapeutics Liaisons

Breast Committee Liaison: Stephanie L. Graff, MD
 Cancer Control Liaison: Jason M. Prosek, MD
 Lara E. Davis, MD
 Genitourinary Committee Liaison: Neeraj Agarwal, MD
 Imaging: TBD
 Lung Committee Liaison: Shirish M. Gadgeel, MD
 Lymphoma Committee Liaison: Nasheed Mohammad Hossain, MD
 Melanoma Committee Liaison: Jeffrey A. Sosman, MD
 Myeloma Committee Liaison: Frits van Rhee, MD, PhD

Time/Location

Thursday, October 12, 2023 10:00 a.m. - 12:15 p.m.
 Room: Regency D (Ballroom Level, West Tower)

Agenda

10:00 - 10:05 am Welcome and Introduction - Razelle Kurzrock, MD
 10:05 - 10:25 am Updates from Sarcoma Working Group - Lara Davis, MD
 10:25 - 10:45 am S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas" - David Zhen, MD
 10:45 - 11:10 am CIMAC and Translational Immunology in DART - Young Kwang Chae, MD

11:10 - 11:30 am Translational Findings from Non-Pancreatic Neuroendocrine DART Cohorts from CIMAC - Cara Haymaker, PhD
 11:30 - 11:50 am Update from CNS Working Group - Manmeet Ahluwalia, MD
 11:50 - 12:10 pm ComboMATCH - speaker TBD
 12:10 - 12:15 pm Wrap Up - Razelle Kurzrock, MD

Active Studies

S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC)." Drs. Zhen, Chiorean, Burgess, Swisher. Activated: 12/2/21.

CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma." Dr. Uboho. SWOG Champion: Dr. Saeed. Activated: 2/6/20.

CTSU/EA3163, "Phase II Randomized Trial of Neoadjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a (and Selected T4b) Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)." Dr. Saba. SWOG Champion: Dr. Swiecicki. Activated: 3/28/18.

CTSU/A071601, "Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas." Dr. Brastianos. SWOG Champion: Dr. Ahluwalia. Activated: 8/4/17. Temporarily Closed (Cohort A): 9/8/20.

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations." Dr. Brastianos. SWOG Champion: Dr. Piccioni. Activated: 8/28/2015. New patient registration (Step 1) to the NF2, CDKN2A, CDK4, CDK6, CCND1, CCND2, CCND3, and CCNE1 Cohort (Abemaciclib Cohort) is closed to accrual as of 10/03/2022.

CTSU/A092001, "Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma". SWOG Champion: Dr. P.S.K. Raghav. Activated: 10/15/21.

CTSU/AGCT1531, "A Phase III Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors" SWOG Champion: Dr. D'Souza. Activated: 5/8/17.

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CTSU/AOST2031, "A Phase 3 Randomized Controlled Trial Comparing Open vs Thoroscopic Management of Pulmonary Metastases in Patients with Osteosarcoma" SWOG Champion: Dr. Hofstetter. Activated: 2/15/22

CTSU/AOST2032, "A Feasibility and Randomized Phase 2/3 Study of the VEGFR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma" SWOG Champion: Dr. J. A. Livingston. Activated: 2/17/23

CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent Glioblastoma." SWOG Champion: Dr. M. Ahluwalia. Activated: 10/30/20

Studies in Development

S2310, "Phase II Randomized Study Testing Non-Inferiority of Shorter-Course Radiation Versus Standard Fractionation for High-Risk, Resectable Sarcoma". Dr. Harris

Closed Studies

S1609, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, and Kurzrock. Activated: 1/13/17. Closed: 3/15/23.

CTSU/NRG-GY006, "A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer." Dr. Leath. SWOG Champion: Dr. Robinson. Activated: 1/15/16. Closed: 9/22/22

CTSU/NRG-GY020, "A Phase III Randomized Trial of Radiation +/- Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer." Dr. Backes. SWOG Champion: Dr. Robinson. Activated: 2/7/20. Closed: 8/29/22.

NCICOVID, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20. Closed: 2/1/2022.

CTSU/NRG-GY009, "A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer." Dr. O'Ceirbhail. SWOG Champion: Dr. Robinson. Activated: 5/12/17. Closed 10/14/2021

CTSU/NRG-HN007, "An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Brigette B. Y. Activated: 9/8/20; Closed: 10/28/21

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Activated: 8/12/2015. Closed: 12/23/2022

CTSU/NRG-BN007, "A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma." Dr. Lassman. SWOG Champion: Dr. Ahluwalia. Activated: 8/6/20. Closed: 3/29/2023.

Proposed Studies

NRG-BN1803, "NRG-COG Phase II Trial of Radiation Plus Concurrent and Adjuvant ONC201 for Newly Diagnosed, H3 K27M-Mutant Gliomas." SWOG Champion: Dr. Ahluwalia.

NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.

NRG-BN1855, "A Randomized Phase II/III Open Label Study of Ipilimumab and Nivolumab Vs Temozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Glioblastoma." Dr. M. Ahluwalia.

NRG-HN1854, "An Open-label, Phase III Study of Platinum-Gemcitabine with or Without Nivolumab in the First-line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. P. Swiecicki.

NRG-UC1805, "Randomized Phase III Trial of Radiation +/- Pembrolizumab for High Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer." Dr. W. Robinson.

ComboMatch

Active Studies

EAY191-S3, "Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors." Study Chairs: Reva Basho, M.D., Haider Mahdi, M.

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

	S1609	S2012	A071401	AGCT1531	EAY131
Ascension Providence Hospitals - Southfield	1	-	-	-	3
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	2	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	3
CWRU Case Comprehensive Cancer Center LAPS	7	-	-	-	10
Cancer Research for the Ozarks NCORP	1	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	3	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	3	-	-	-	-
Cedars-Sinai Medical Center	8	-	-	-	6
City of Hope Comprehensive Cancer Center	2	-	-	-	6
Columbus NCI Community Oncology Research Program	3	-	-	-	-
CommonSpirit Health Research Institute	15	-	1	-	9
Dayton NCI Community Oncology Research Program	2	-	-	-	1
Essentia Health NCI Community Oncology Research Program	4	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	10	2	-	-	2
Georgia NCI Community Oncology Research Program	6	-	-	-	-
Gulf South Minority Underserved NCORP	2	-	-	-	-
Hawaii Minority Underserved NCORP	4	-	-	-	1
Heartland Cancer Research NCORP	15	-	-	-	1
Henry Ford Hospital	17	-	-	-	11
Houston Methodist Hospital	-	-	-	-	1
Intermountain Medical Center	1	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	27	-	-	-	6
Loma Linda University Medical Center	6	-	-	-	1
Loyola University Medical Center	4	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	6	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	4	-	-	-	2
Mercy Medical Center - Des Moines	2	-	-	-	-
Michigan Cancer Research Consortium NCORP	12	2	-	-	-
Mission Hospital	-	-	-	-	3
Moffitt Cancer Center	22	-	-	-	-
Montana Cancer Consortium NCORP	16	-	-	-	-
MultiCare Tacoma General Hospital	2	-	-	-	-
Nevada Cancer Research Foundation NCORP	18	-	-	-	-

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	S1609	S2012	A071401	AGCT1531	EAY131
New Mexico Minority Underserved NCORP	18	-	-	-	-
Northwestern University LAPS	16	-	1	-	-
Oregon Health and Science University	12	-	-	-	-
Pacific Cancer Research Consortium NCORP	12	-	-	-	-
Saint Luke's Hospital of Kansas City	-	-	-	-	1
Southeast Clinical Oncology Research Consortium NCORP	-	1	-	-	5
Sutter Cancer Research Consortium	2	-	-	-	4
The Don and Sybil Harrington Cancer Center	-	-	-	1	-
Tulane University Health Sciences Center	-	-	-	-	1
UC Davis Comprehensive Cancer Center LAPS	11	-	-	-	9
UC Irvine Health/Chao Family Comprehensive Cancer Center	8	-	1	-	19
UC San Diego Moores Cancer Center	27	-	2	-	-
USC Norris Comprehensive Cancer Center LAPS	4	-	-	-	-
University of Arkansas for Medical Sciences	5	-	-	-	3
University of Colorado Cancer Center LAPS	6	-	1	-	9
University of Kansas Cancer Center - MCA Rural MU NCORP	35	-	-	-	6
University of Kentucky/Markey Cancer Center	-	-	-	-	13
University of Michigan Comprehensive Cancer Center LAPS	32	-	-	-	24
University of Mississippi Medical Center	5	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	3	-	-	-	-
University of Rochester LAPS	5	-	-	-	-
University of Texas Health Science Center at San Antonio	5	-	-	-	7
University of Texas MD Anderson Cancer Center LAPS	19	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	3	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	4	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	1	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	3
Wisconsin NCI Community Oncology Research Program	12	-	-	-	-
Yale University - Yale Cancer Center LAPS	7	-	2	-	13
ALLIANCE	106	6	-	-	-
ECOG-ACRIN	78	-	-	-	-
NRG	138	3	-	-	-
Total	798	15	8	1	183