

SPRING GROUP MEETING

Seattle

Early Therapeutics & Rare Cancers Committee

APRIL 3-6, 2024 | SEATTLE, WASHINGTON

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 (Survivorship)
 Genitourinary Committee Liaison: Parminder Singh, 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, April 4, 2024 10:30 a.m. - 12:30 p.m.
 Room: Columbia D (Level 3)

Agenda

10:30 - 10:35 am Welcome and Introduction - Razelle Kurzrock, MD
 10:35 - 10:55 am Updates from Sarcoma Working Group - Lara Davis, MD
 10:55 - 11:15 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
 11:15 - 11:35 am CIMAC and Translational Immunology in DART - Young Chae, MD

11:35 - 11:55 am Clinical Update: DART Results - Sandip Patel, PhD
 11:55 - 12:10 pm Update from CNS Working Group - Manmeet Ahluwalia, MD
 12:10 - 12:25 pm ComboMatch Update – Reva Basho, MD
 12:25 - 12:30 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/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. Stratum 2 is temporarily closed to accrual 10/19/23

CTSU/AOST2031, "A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic 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

Early Therapeutics & Rare Cancers Committee

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 Hyper-mutated Recurrent Glioblastoma.” SWOG Champion: Dr. M. Ahluwalia. Activated: 10/30/20. Pre-Registration is temporarily Closed to accrual 12/12/23

CTSU/HN.11 (CCTG-HN11), “SPECT-CT Guided Elective Contralateral Neck Treatment (SELECT) for Patients with Lateralized Oropharyngeal Cancer: A Phase III Randomized Controlled Trial SWOG” Champion: Dr. Paul Swiecicki. Activated: 9/29/22

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

S2425, “A Randomized Phase II Study of Temozolomide in Combination with Atezolizumab (Tem-Atezo) versus Temozolomide Alone in Adults with Advanced Bronchopulmonary Neuroendocrine Tumors.” Dr. Sukrithan

S2426, “A Randomized Phase II Study of Amivantamab versus Cetuximab in Immunocompromised Patients with Recurrent Inoperable or Metastatic Cutaneous Squamous Cell Carcinoma”. Dr. Swiecicki.

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.

NICCOVID, “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’Cearbhaill. 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. Brigitte 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: 3/29/23.

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. Closed: 11/7/23

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 Te-mozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-Methylguanine DNA Methyltransfer-ase) 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.

Early Therapeutics & Rare Cancers Committee

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.

Publications

The publications listed below were received by the Group Chair’s Office as published (including online), accepted, or submitted since the SWOG Fall 2023 Group Meeting. Conference abstracts are not included.

Because of journal embargo policies, journal names are omitted for submitted or accepted manuscripts.

Published/Accepted Manuscripts

S1609 A phase II basket trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART SWOG 1609 Cohort 47) in patients with gestational trophoblastic neoplasia. Patel S, Othus M, Chae Y, Dennis M, Gordon S, Mutch D, Samlowski W, Robinson W, Sharon E, Ryan C, Lopez G, Plets M, Blanke C, Kurzrock R. *Clinical Cancer Research* Jan 5;30(1):33-38, 2024. <https://pubmed.ncbi.nlm.nih.gov/37882676/>

S1609 Correlation Between Tumor Size Change and Outcome in a Rare Cancer Immunotherapy Basket Trial. Othus M, Patel S, Chae YK, Streicher H, Sharon E, Kurzrock R. *Journal of the National Cancer Institute* Jan 18:djia009. doi: 10.1093/jnci/djia009. Online ahead of print, 2024. <https://pubmed.ncbi.nlm.nih.gov/38243705/>

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART SWOG 1609 Cohort 48) in Patients with Advanced Gallbladder Cancer. Patel S, Guadarrama E, Chae Y, Dennis M, Powers B, Liao C-Y, Ferri W, George T, Sharon E, Ryan C, Othus M, Lopez G, Blanke C, Kurzrock R. *Cancer* Feb 15. doi: 10.1002/cncr.35243. Online ahead of print, 2024. <https://pubmed.ncbi.nlm.nih.gov/38358334/>

Submitted Manuscripts

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: The Salivary Gland Tumor Cohort. Chae Y, Sun R, Patel S, Giles F, Ohr J, Worden F, Suga J, Naing A, Cohen E, Wallace J, Fenton S, Il-Young Chung L, Kang H, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Othus M, Blanke CD, Kurzrock R. Submitted 2023.

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: Adrenocortical Carcinoma Cohort., Patel S, Othus M, Chae Y, Huynh T, Tan B, Kuzel T, Vogelzang N, McLeod C, Lopez G, Chen H, Sharon E, Streicher H, Ryan C, Blanke C, Kurzrock R. Submitted, 2024.

S1609 SWOG/NCI S1609 Phase II Basket Trial Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART): Non-Epithelial Ovarian Cancer. Chae Y, Othus M, Patel S, Wilkinson K, Whitman-Purves E, Lea J, Schallenkamp J, Adra N, Appleman L, Alden M, Thomes Pepin J, Ellerton J, Poklepovic A, Walter A, Rampurwala M, Robinson W, Il-Young Chung L, Kim H, McLeod C, Lopez G, Chen H, Sharon E, Streicher H, Ryan C, Blanke C, Kurzrock R. Submitted 2023.

S1609 Phase II Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG/NCI Experience: Invasive Mucinous or Non-mucinous Lepidic Adenocarcinoma of the Lung (Formerly Bronchioloalveolar Carcinoma). Chae Y, Othus M, Patel S, Gerber D, Tanvetyanon T, Il-Young Chung L, Kim H, McLeod C, Lopez G, Chen H, Sharon E, Streicher H, Ryan C, Blanke C, Kurzrock R. Submitted, 2024.

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: The Desmoid Tumors. Chae Y, Othus M, Patel S, Powers B, Hsueh C, Govindarajan R, Bucur S, Kim H, Il-Young Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Blanke CD, Kurzrock R. Submitted, 2024.

S1609 DART/SWOG/NCI Phase II Anti-CTLA-4/PD-1 Trial: Clear Cell Carcinomas of Ovary, Endometrium, Cervix. Chae Y, Othus M, Patel S, Backes F, O’Malley D, Cristea M, Naing A, Kurnit K, Eskander R, Goodrich S, Robinson W, Kim H, Il-Young Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Blanke CD, Kurzrock R. Submitted, 2024.

Early Therapeutics & Rare Cancers Committee

Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	EAY191-S3	S1609	S2012	A071401	AGCT1531	EAY131	EAY191	EAY191E4
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	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	3	-	-	2	-	-
Georgia NCI Community Oncology Research Program	-	6	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	2	1	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	4	-	-	-	1	-	-
Heartland Cancer Research NCORP	-	15	-	-	-	1	-	-
Henry Ford Hospital	-	17	2	-	-	11	-	-
Houston Methodist Hospital	-	-	-	-	-	1	-	-
Intermountain Medical Center	-	1	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	27	1	-	-	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	2	-	-	-	-	-
Montana Cancer Consortium NCORP	-	16	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	1	-	-	-
MultiCare Tacoma General Hospital	-	2	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	18	-	-	-	-	-	-

Early Therapeutics & Rare Cancers Committee

Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	EAY191S3	S1609	S2012	A071401	AGCT1531	EAY131	EAY191	EAY191E4
New Mexico Minority Underserved NCORP	-	18	-	-	-	-	-	-
Northwestern University LAPS	-	16	2	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 School of Medicine	-	-	-	-	-	1	-	-
UC Davis Comprehensive Cancer Center LAPS	-	11	-	-	-	9	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	8	-	1	-	19	3	3
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	1	-	-	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	1	19	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	3	1	-	-	-	-	-
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	8	-	-	-	-	-
ECOG-ACRIN	-	78	1	-	-	-	-	-
NRG	-	138	5	-	-	-	-	-
Total	1	798	32	8	2	183	3	3

