

# San Francisco

## Spring Group Meeting

# SPECIALS

Early Therapeutics & Rare Cancers  
Committee

# 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  
 ..... Sara Threlkel, BS

## Designates

Data Coordinator: ..... Christine Magner  
 Digital Engagement: ..... Kanwal Raghav, MD, MBBS  
 Veterans Affairs: ..... Jimmy Ruiz, MD  
 Oncology Research Professionals:  
     CRAs: ..... TBD  
     Nurse: ..... Adam Platt, BS  
 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: ..... TBD  
 Myeloma Committee Liaison: ..... Frits van Rhee, MD, PhD

## Time/Location

Thursday, May 1, 2025 9:00 a.m. - 11:00 a.m.  
 Room: Seacliff AB (Bay Level)

## Agenda

9:00 – 9:05 am Welcome and Introduction - Razelle Kurzrock, MD  
 9:05 – 9:25 am CNS Working Group and DART CNS Data - Manmeet Ahluwalia, MD  
 9:25 – 9:45 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

9:45 – 10:05 am Translational Aspects of DART - Young Kwang Chae, MD, MPH  
 10:05 – 10:25 am Overview of Clinical Updates of DART - Sandip Patel, MD  
 10:25 – 10:45 am Updates from Sarcoma Working Group - Lara Davis, MD  
 10:45 – 10:55 am NEC-BiTe: A phase II randomized trial of tarlatamab in patients with extrapulmonary neuroendocrine carcinoma - Junaid Arshad, MD, MS  
 10:55 – 11:00 am 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. Ubobo. SWOG Champion: Dr. Saeed. Activated: 2/6/20.

**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 12/17/2024.

**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 Chemotherapy for Newly Diagnosed Osteosarcoma" SWOG Champion:



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Dr. J. A. Livingston. Activated: 2/17/23 Temporarily Closed to Accrual as of 09/06/2023

**CTSU/A071702**, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatic 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

**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.

**S2505**, "Phase III Randomized Study Testing Non-Inferiority of Short-Course Ultra-Fractionated Radiation (UHRT-5) Versus Standard Fractionation (RT-25) for High-Risk, Resectable Soft Tissue Sarcoma. Dr. Harris

## Closed Studies

**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. Closed: 05/10/2024

**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.

**NCIC019**, "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'Ceirhaill. 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 Temozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Glioblastoma." Dr. M. Ahluwalia.

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**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 Proposed Studies

**EAY191-S7**, "A Phase 2 Study Investigating Safety and Efficacy of Trastuzumab Deruxtecan (DS8201/T-DXd) and ATR Inhibitor, Ceralasertib (AZD6738) in Human Epidermal Growth Factor Receptor 2 (HER2) Positive Advanced Solid Tumors." Dr. K. Raghav.

## 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 2024 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 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. J Immunother Cancer Sep 28;12(9):e009128, 2024. <https://pubmed.ncbi.nlm.nih.gov/39343510/>

**S1609** A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors SWOG S1609: Vulvar Cancers. Chae YK, Corthell L, Patel SP, Edwards R, Scalici JM, Kim HS, Chung LI, Othus M, McLeod CM, Chen HX, Sharon E, Streicher H, Ryan CW, Blanke CD, Kurzrock R. Clin Cancer Res. Jan 17;31(2):308-315, 2025. <https://pubmed.ncbi.nlm.nih.gov/39561273/>

**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. Ther Adv Med Oncol. Nov 22;16:17588359241293401, 2024.

<https://pubmed.ncbi.nlm.nih.gov/39583952/>

**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. Clin Cancer Res. Dec 16;30(24):5593-5600, 2024.

<https://pubmed.ncbi.nlm.nih.gov/39417692/>

**S1609** First Cycle Toxicity and Survival in Patients with Rare Cancers Treated with Checkpoint Inhibitors Othus M, Patel S, Chae YK, Deitrich E, Streicher H, Sharon E, Kurzrock R. J Natl Cancer Inst. 2024 Nov 20:djae297. <https://pubmed.ncbi.nlm.nih.gov/39565908/>

**S1609** Dual anti-CTLA-4 and anti-PD-1 blockade in metastatic basal cell carcinoma. Patel SP, Cano-Linson E, Chae YK, Schokrpur S, Lao CD, Powers BC, Victor AI, Onitilo AA, Shin S, Takebe N, Threlkel S, McLeod CM, Chen HX, Sharon E, Othus M, Ryan CW, Blanke CD, Kurzrock R. NPJ Precis Oncol. 2025 Jan 24;9(1):24. <https://pubmed.ncbi.nlm.nih.gov/39856213/>

**S1609** A phase II basket trial of dual anti-CTLA-4 and anti-PD-1 blockade in rare tumors (DART) SWOG S1609: durable responses and delayed pseudoprogression in small cell carcinoma of the ovary, hypercalcemic type cohort. Chae YK, Othus M, Patel SP, Aljumaily R, Win K, Pejovic T, Thomas S, Robinson W, Kim H, Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Blanke C, Kurzrock R. Accepted.

## 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.

**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.

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**Accrual from trials that are open as of 12/31/2024 or have closed in the prior 18 Months by Institution and Study**

	EAY191-S3	S2012	A071401	AGCT1531	EAY191	EAY191A3	EAY191A6	EAY191E4
Cancer Research Consortium of West Michigan NCORP	-	1	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	1	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	1	-	-	-
CommonSpirit Health Research Institute	-	1	1	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS	1	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	10	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	1	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	1	-	-	-	-	-	-
Henry Ford Hospital	-	2	-	-	-	-	-	-
Kaiser Permanente NCI Comm Oncology Research Program	-	3	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	3	-	-	-	-	-	-
Moffitt Cancer Center	-	4	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	1	-	-	-	-
Northwestern University LAPS	-	4	1	-	-	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	5	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	1	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	1	-	-	-	-	-	-
The Don & Sybil Harrington Cancer Center	-	-	-	1	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	-	4	-	1	3
UC San Diego Moores Cancer Center	-	-	2	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	1	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	2	-	-	-	-	-	-
University of Texas Health Science Center at San Antonio	-	2	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	1	-	-	-	6	2	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	1	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	2	-	-	-	-	-	-
Wisconsin NCI Comm Oncology Research Program	-	1	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	4	2	-	-	-	-	-
ALLIANCE	1	11	-	-	-	-	-	-
ECOG-ACRIN	4	7	-	-	-	-	-	-
NRG	-	7	-	-	-	-	-	-
<b>Total</b>	<b>8</b>	<b>74</b>	<b>8</b>	<b>2</b>	<b>11</b>	<b>2</b>	<b>1</b>	<b>3</b>

