

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
..... Melissa Plets, MS
..... Edward Mayerson, MS

Designates

Data Coordinators: 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 Mireles
Clinical Trials Program Manager: Michelle Maxim
Early Therapeutics Liaisons
Breast Committee Liaison: TBD
Cancer Control Liaison: Jason M. Prosek, 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, April 7, 2022 10:00 am - 12:15 pm
Room: Columbia D, Level 3

Agenda

Introduction

10:00 - 10:05 am: Razelle Kurzrock, M.D., Chair, Early Therapeutics and Rare Cancer Committee (SWOG).

Presentations

10:05 - 10:20 am: "Updates from Sarcoma Working Group" - Lara Davis, M.D., Associate Professor Knight Cancer Institute, Co-Leader, Translational Oncology Research Program, Sarcoma Disease Site Leader, Knight Cancer Institute, Oregon Health & Science University.

10:20 - 10:35 am: "Update on Sarcoma Concept" - Michael Wagner, M.D., Assistant Professor, Division of Medical Oncology, University of Washington, Fred Hutchinson Cancer Research Center.

10:35 - 10:55 am: "Updates from CNS Working Group." - Manmeet Ahluwalia, M.D., Chief of Medical Oncology, Deputy Director, Chief Scientific Officer, Miami Cancer Institute.

10:55 - 11:15 am: "CIMAC and Translational Immunology in DART." - Young Chae, M.D., Vice Chair, Early Therapeutics and Rare Cancers (SWOG), Northwestern University, Robert H. Lurie Comprehensive Cancer Center.

11:15 - 11:35 am: "DART: Clinical Trial Updates." - Sandip Patel, M.D., Associate Professor Deputy Director, San Diego Center for Precision Immunotherapy, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA

11:35 - 11:55 am: "New Drugs in Oncology." - Monica Mita, M.D., Professor of Medicine, Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center.

11:55 am - 12:10 pm: "New Approved Study: 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)" - David Zhen, M.D., Assistant Professor of Medicine, University of Washington, Fred Hutchinson Cancer Research Center.

12:10 - 12:15 pm: Wrap Up. Razelle Kurzrock, M.D., Chair, Early Therapeutics and Rare Cancer Committee (SWOG).

Active Studies

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

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

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

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; Temporarily Closed: 10/28/21

Early Therapeutics & Rare Cancers Committee

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.

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.

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. Temporarily Closed: 6/15/21.

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/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.

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.

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.

Proposed Studies

S2208, "Neoadjuvant Nivolumab and Paclitaxel Followed by Definitive Local Control for Patients with Locoregional Angiosarcoma." Dr. Wagner.

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

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

NRG, SWOG study in HPV-associated malignancies by the use of AZD2811, an Aurora B kinase inhibitor, and MEDI4736, anti-PD-L1. Dr. Fu.

Closed Studies

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'Ceirbhail. SWOG Champion: Dr. Robinson. Activated: 5/12/17. Closed 10/14/2021

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.

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.

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.

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

NRG, SWOG study in HPV-associated malignancies by the use of AZD2811, an Aurora B kinase inhibitor, and MEDI4736, anti-PD-L1. Dr. Fu.

Early Therapeutics & Rare Cancers Committee

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

| | 51609 | 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 | 6 | - | 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 | 17 | - | 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 |
| Georgia NCI Community Oncology Research Program | 6 | - | - |
| Gulf South Minority Underserved NCORP | 2 | - | - |
| Hawaii Minority Underserved NCORP | 3 | - | 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 | 5 | - | - |
| Medical University of South Carolina Minority Underserved NCORP | 4 | - | 2 |
| Michigan Cancer Research Consortium NCORP | 12 | - | - |
| Moffitt Cancer Center | 22 | - | - |
| Montana Cancer Consortium NCORP | 16 | - | - |
| MultiCare Tacoma General Hospital | 2 | - | - |
| Nevada Cancer Research Foundation NCORP | 18 | - | - |
| New Mexico Minority Underserved NCORP | 17 | - | - |

Early Therapeutics & Rare Cancers Committee

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

| | S1609 | AGCT1531 | EAY131 |
|---|------------|----------|------------|
| Northwestern University LAPS | 16 | - | - |
| Oregon Health and Science University | 11 | - | - |
| Pacific Cancer Research Consortium NCORP | 12 | - | - |
| Saint Luke's Hospital of Kansas City | - | - | 1 |
| Southeast Clinical Oncology Research Consortium NCORP | - | - | 8 |
| 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 | - | 19 |
| UC San Diego Moores Cancer Center | 27 | - | - |
| USC Norris Comprehensive Cancer Center LAPS | 4 | - | - |
| University of Arkansas for Medical Sciences | 5 | - | 3 |
| University of Colorado Cancer Center LAPS | 6 | - | 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 | 2 | - | - |
| 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 | - | - |
| Wayne State University - Karmanos Cancer Institute LAPS | - | - | 3 |
| Wisconsin NCI Community Oncology Research Program | 12 | - | - |
| Yale University - Yale Cancer Center LAPS | 7 | - | 13 |
| ALLIANCE | 105 | - | - |
| ECOG-ACRIN | 78 | - | - |
| NRG | 136 | - | - |
| Total | 789 | 1 | 183 |