Leadership
Chair: Lajos Pusztai, MD, PhD
Vice-Chair:Priyanka Sharma, MD
Executive Officer: Anne Chiang, MD, PhD
Statisticians:William E. Barlow, PhD
Danika Lew, MA
Jieling Miao, MS
Scientific Leadership
Translational Medicine: Alastair M. Thompson, MD
Andrew K. Godwin, PhD
Radiation Oncology:
Surgery: Joshua M.V. Mammen, MD, PhD
Imaging:Joanne E. Mortimer, MD
Pathology:
Early Therapeutics:Stephanie L. Graff, MD
Designates
Cancer Control Liaisons: Melinda L. Irwin, PhD, MPH (Survivorship)
Dawn L. Hershman, MD (Cancer Care Delivery)
Helen K. Chew, MD (Symptom Control & QOL)
DEI Champion:Gayathri Nagaraj, MD
Digital Engagement: Sarah S. Mougalian, MD
NCORP Representative:
Data Coordinators:
Larry Kaye
Ojasvi Mittal
Gabi Herbert
Oncology Research Professionals:
CRAs: Karyn N. Hart, CCRP
Nurse:
Patient Advocates: Roberta A. Albany
Ginny Mason, RN, BSN
Pharmaceutical Science: Jorge G. Avila, PharmD
Dawud Nael Dawud Ellayan, Pharm D
Protocol Project Manager:
Clinical Trials Program Manager:
j j

#### Time/Location

Loodovabiu

Saturday, October 22, 2022 9:15 am - 12:15 pm Room: Regency B (Ballroom Level, West Tower)

#### Agenda

- 9:30 9:35 am Welcome and Introductions Lajos Pusztai, M.D., D.Phil. (Chair) and Priyanka Sharma, M.D. (Vice-chair)
- 9:35 10:35 am Mini symposium "Improving Diversity in Clinical Trials Bridging Gaps and Creating Opportunities"
- Facilitator Andrew K. Godwin, PhD: Professor and Division Director,
  Genomic Diagnostics; Deputy Director, University of Kansas
  Comprehensive Cancer Center, & Founding Director, Kansas Institute for
  Precision Medicine, University of Kansas Medical Center).
- <u>9:35 9:50 am</u> "Improving Diversity in Clinical Trials: Why, What and How?" Gayathri Nagaraj, MD Associate Professor of Medicine and Breast Medical Oncologist at Loma Linda University Cancer Center.
- <u>9:50 10:00 am</u> Interactive questions "Diversity, Equity, and Inclusion in Clinical Trials: What are You Doing at Your Institute?"
- 10:00 10:15 am "Engaging Communities and Providers to Enhance Clinical Trials Access" - Hope Krebill, MSW, BSN, RN: Executive Director, Masonic Cancer Alliance, the University of Kansas Cancer Center) & Ronald Chen, MD, MPH, FASCO, FASTRO: Professor and Chair, Radiation Oncology, the University of Kansas Medical Center.
- 10:15 10:30 am "Building Trust and Relationships: A Patient Prospective" Roberta Albany: Patient Advocate SWOG Breast Committee
- 10:30 10:35 am "Plan of Action" Gayathri Nagaraj, MD
- 10:35 10:45 am Publication update William Barlow, Ph.D.
- 10:45 10:55 am Advocate update Ginny Mason & Roberta Albany
- **10:55 11:05 am Translational Medicine Sub-Committee update** Alastair Thompson, M.D. & Andrew K. Godwin, Ph.D.
- 11:05 11:45 am Review of open CTSU trials
- 11:45 12:05 pm Recently approved and developing Concepts
- 12:05 12:25 pm Reports from Committee Liaisons

Radiotherapy - Reshma Jagsi, M.D.

Surgery – Joshua Mammen, M.D.

Cancer Survivorship - Melinda L. Irwin, Ph.D., M.P.H.

Cancer Care Delivery - Dawn Hershman, M.D.

Prevention – Banu Arun, M.D.

Symptom Control & QOL - Helen K. Chew, M.D.

NCORP - Philip Lammers, M.D.

DEI - Gayathri Nagaraj, M.D.

12:25 - 12:30 pm Closing Comments and Adjourn



#### **Proposed Studies**

- S2212, "Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), a Randomized Phase III Study." Drs. Sharma and Mitri.
- <u>S2206</u>, "Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer." Drs. Cobain and Pusztai.

#### **Active Studies**

- <u>S2007</u>, "A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases." Drs. Brenner and Kaklamani. Activated: 12/15/20.
- S1706, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Drs. Jagsi and Chalasani. Activated: 09/12/18.
- CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 02/07/14. Temporarily closed: 01/14/2022.
- CTSU/A011801, "The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib." Dr. O'Sullivan. SWOG Champion: Dr. Murthy. Activated: 01/06/21.
- CTSU/CCTG MA.39, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 05/30/18.
- CTSU/EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu. Activated: 02/11/20.
- CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG

- Champions: Breast Committee: Dr. Linden, Imaging Committee: Dr. Wright. Activated: 04/02/20.
- CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14. Temporarily closed: 09/13/19.
- CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG Champion: Dr. Makhoul. Activated: 06/26/15.
- CTSU/NRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Taxane/ Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 03/12/19.
- CTSU/NRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 04/13/17. Temporarily closed: 07/02/19.
- CTSU/NRG-BR007, "A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)." Dr. White. SWOG Champion: Dr. Shumway. Activated: 06/07/21.

#### **Closed Studies**

- <u>S1418</u>, "A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy." Drs. Pusztai and Mammen. Activated: 11/15/16. Permanently closed: 06/30/21.
- <u>S1207</u>, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e^3 Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Pusztai. Activated: 09/04/13. Permanently closed: 05/01/19.



# Tweeting the Meeting

Twitter is a major venue you can use to get out word about what you learn at the group meeting.

@SWOG has more than 12K followers and can amplify your message!

Follow SWOG at twitter.com/SWOG

With your group meeting tweets ...

tag your @SWOG friends

use the hashtag #SWOGonc



## **Breast Committee**

#### **Active Cancer Survivorship Study**

<u>\$1501</u>, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III." Drs. Floyd and Leja. Activated: 09/15/17.

#### **Active Symptom Control and Quality of Life Studies**

S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang and Lok. Activated: 02/21/19.

S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi and Hershman. Activated 03/01/19.

#### **Active Cancer Care Delivery Studies**

<u>S1703</u>, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer." Drs. According and Hershman. Activated: 07/16/18.

CTSU/EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Pisano. SWOG Champion: Dr. Arun. Activated: 07/06/17.

#### **Active Cancer Prevention Study**

S1904, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, and Kukafka. Activated: 09/01/20.

#### **Active Early Therapeutics and Rare Cancers Studies**

<u>\$1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 01/13/17.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Flaherty. Activated 08/12/15.



## Accrual from trial opening through 6/30/2022 by Institution and Study

	51418	51706	52007	A011202	A011401	A011801	EA1131	EA1181	EA1183	MA39	NRGBR003	NRGBR004	NRGBRO
Ascension Prov Hosp - Southfield	6	2	-	4	10	-	1	2	-	1	3	1	-
Ascension Via Christi Hosp Wichita	9	-	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	3	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	4	1	-	1	6	-	-	6	-	-	-	-	-
Baptist Mem HC/Mid South MU NCORP	9	3	-	1	4	-	-	1	-	-	-	1	-
Bay Area Tumor Inst NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-
Baylor U Med Ctr	-	-	-	1	-	-	-	-	-	-	-	-	-
Boston Med Ctr	-	-	-	-	3	-	-	10	-	-	-	-	-
CWRU Case CCC LAPS	12	-	1	-	2	-	-	-	-	1	9	1	-
Ca Res Consortium of West Mich NCORP	24	-	-	-	1	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	9	1	-	-	1	1	-	-	-	-	3	-	-
Ca Res of Wisconsin & N Mich Consort	7	-	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	3	-	1	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	9	-	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	8	2	-	-	-	-	-	3	-	-	-	-	-
Columbus NCORP	13	-	-	-	-	-	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	19	1	-	-	2	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail Hlth	-	-	-	1	1	-	-	-	-	-	1	-	-
Dayton NCORP	3	-	-	-	1	-	1	7	-	-	-	-	-
Desert Regional Med Ctr	1	-	-	7	4	-	-	-	-	-	-	-	-
Essentia Health NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	10	3	-	-	12	-	-	-	-	-	-	-	-
Georgia NCORP	23	2	-	-	2	-	4	-	-	-	1	-	-
Gulf South MU NCORP	5	1	-	-	-	-	-	2	-	-	4	-	-
Hawaii MU NCORP	5	-	-	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	19	3	-	-	-	1	-	-	-	-	-	-	-
Henry Ford Hospital	1	-	-	-	-	-	1	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	1	-	-	-	-	-	-	-
Kaiser Permanente NCORP	51	-	-	1	55	-	-	-	-	-	25	1	-
Lahey Hospital & Med Ctr	3	-	-	-	9	-	1	4	-	-	-	1	-
Loma Linda U Med Ctr	1	-	-	3	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	3	-	-	-	6	-	2	1	-	-	-	-	-
Medical U South Carolina MU NCORP	11	-	-	-	-	-	-	-	3	-	-	-	-
Meharry Medical College	-	-	-	-	3	-	-	-	-	-	1	-	-
Michigan Ca Res Consortium NCORP	21	1	-	-	-	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	1	3	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	2	3	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	3	-	-	-	-	-	-	1	-	-	-	-	-
NCORP Carolinas (Prisma HIth NCORP)	4	-	-	-	-	-	-	-	-	-	-	-	-
Nevada Ca Res Foundation NCORP	11	-	_		_	-	_	-	_	_	_	_	_



### Accrual from trial opening through 6/30/2022 by Institution and Study

	51418	51706	52007	A011202	A011401	A011801	EA1131	EA1181	EA1183	MA39	NRGBR00	NRGBROO	4 NRGBRO
New Mexico MU NCORP	19	4	1	-	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	1	-	-	-	-	-	-	-	-	-	1
Northwestern U LAPS	2	1	-	-	-	-	-	2	1	-	1	-	-
Ohio State U CCC LAPS	-	1	-	-	-	-	-	-	-	-	-	-	-
Oregon Health & Science U	19	-	-	-	-	-	-	-	3	-	3	-	-
Orlando Health Ca Inst	1	-	-	-	1	-	-	-	-	-	-	-	-
Pacific Ca Res Consortium NCORP	19	-	-	-	3	-	-	-	-	-	1	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	1	-	-	-	-	-	-	-	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-	-	-
Scott & White Mem Hospital	-	-	-	-	4	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	46	-	-	-	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	3	-	-	-	8	2	1	3	-	-	4	2	-
The Don and Sybil Harrington CC	7	3	-	11	8	2	-	-	-	-	-	-	-
James Graham Brown CC, U of Louisville	-	-	-	2	-	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	9	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	8	5	-	2	4	-	-	4	-	-	-	1	-
UC Irvine HIth/Chao Family CCC	6	-	1	3	2	-	-	-	-	-	1	-	-
UC San Diego Moores CC	-	-	-	-	2	-	-	-	-	-	1	-	-
USC Norris CCC LAPS	3	-	-	4	-	-	-	-	-	2	-	-	-
U Arkansas for Medical Sciences	17	2	-	-	3	-	-	-	-	-	-	-	-
U Colorado CC LAPS	11	1	-	42	27	1	-	11	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	22	2	-	4	23	-	-	-	-	1	-	-	-
U Michigan CCC LAPS	13	2	-	-	14	-	-	1	-	4	3	-	-
U Mississippi Med Ctr	-	-	-	-	-	-	-	1	-	-	-	-	-
U Oklahoma HSC LAPS	2	-	-	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	2	1	-	-	-	-	7	1	-	-	9	-	-
U Texas HSC at San Antonio	5	-	1	6	2	-	-	-	-	-	4	-	-
U Texas MD Anderson CC LAPS	21	1	-	-	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	6	2	-	-	7	1	-	3	-	-	-	-	-
Upstate Carolina Consortium NCORP	8	-	-	-	1	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	1	-	-	-	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	3	-	-	11	12	-	6	12	3	-	6	-	-
Western States Ca Res NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	1	-	-	6	5	-	-	-	-	-	-	-	-
Wisconsin NCORP	2	1	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	8	-	-	5	81	1	6	7	-	-	9	1	-
ALLIANCE	144	10	4	-	-	-	-	-	-	-	-	-	-
CCTG	39	6	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	129	5	1	-	-	-	-	-	-	-	-	-	-
NRG	307	34	_	-	-	-	-	-	-	-	-	-	-
Total	1,195	104	11	129	333	10	30	82	10	10	89	9	1

