

E-Newsletter | May 2, 2023 | Vol 13, No 1

# **Alliance to Elect New Group Chair**



Evanthia Galanis, MD



Richard M. Stone. MD

The Board of Directors of the Alliance for Clinical Trials in Oncology will elect a new Group Chair at the upcoming 2023 Alliance Spring Virtual Group Meeting that will take place May 3-6. Two candidates, put forth by the Alliance Group Chair Nominating Committee chaired by **Jeffrey Kirshner, MD**, have been nominated. The successful candidate will serve a six-year term and will succeed Interim Group Chair **Suzanne George, MD**, who assumed the role after **Monica M. Bertagnolli, MD**, was appointed to serve as President Joe Biden's pick for Director of the National Cancer Institute in 2022.

The candidates for Alliance Group Chair are:

**Evanthia Galanis, MD** - As a distinguished researcher, Dr. Galanis leads several national and international collaborations for cancer research. She is the Sandra J. Schulze Professor of Novel Therapeutics, a Professor of Medicine, and has joint consultant appointments in the Division of Medical Oncology - Department of Oncology, and the Department of Molecular Medicine at the Mayo Clinic. She also serves as Chair of the Alliance Neuro-Oncology Committee and is Co-Chair of the Glioblastoma Working Group and U.S. lead for the international rare brain tumor initiative.

Dr. Galanis' laboratory focus is to develop and optimize novel virotherapy approaches in the treatment of cancer with special emphasis on paramyxoviruses. Her laboratory tests different strategies, including use of therapeutic transgenes; trackable markers; combinations with small molecules, cytotoxic agents and radiation therapy; re-targeting of viral strains against tumor-specific antigens; development of novel viral delivery approaches; and exploration of immunomodulatory methods to modify humoral and innate immunity as a means of optimizing virotherapy efficacy.

**Richard M. Stone, MD -** As an expert in the field of leukemia, Dr. Stone is the Lunder Family Chair in Leukemia and a Professor of Medicine at the Harvard Medical School. He is also Chief of Staff, Director of the Adult Leukemia Program, Director of Translational Research in the Adult Leukemia Division, and President of the Hospital Medical Staff at the Dana-Farber Cancer Institute. In addition, he is Associate Director of the Dana-Farber Cancer Institute Medical Oncology Fellowship Program and has served as Chair of the Alliance Leukemia Committee (2011-2022).

Dr. Stone engages in developmental therapeutics for patients with bone marrow stem cell disorders, including the acute leukemias, myelodysplasia, and the myeloproliferative disorders. The areas of differentiation-based therapy, as well as cell signal modification therapy (kinase inhibitors) currently with agents which act on protein kinase-C and immunologically-based therapy involving transduction of pro-inflammatory genes into leukemia cells and dendritic cell/leukemia cell fusions, represent an important current translocational focus.

Results of the Group Chair election will be announced during the Alliance Plenary Session on Friday, May 5. The successful Group Chair candidate will also be eligible to stand for election, as the President of the Alliance for Clinical Trials in Oncology Foundation.

The role of the Alliance Group Chair is responsible for all scientific, financial, and administrative activities of the Alliance and chairs the Alliance Board of Directors and Executive Committee. The Group Chair serves as principal investigator of the Alliance NCI National Clinical Trials Network (NCTN) grant, NCI Community Oncology Research Program grant, other federal and nonfederal grants, and contracts that support the Alliance infrastructure and programs. The Group Chair oversees the activities of the Alliance programs and works with the Group Statistician and Alliance Program Principal Investigators. The Alliance programs include Statistics and Data Management, Central Protocol Operations, Translational Research, Cancer Control, and Procedure-Based Therapy.

### **Leadership Transitions**



Jennifer (Jenny) M. Darcy

**Jennifer (Jenny) M. Darcy** has retired from her Alliance role as Director of the Data Coordination Unit at the Alliance Statistics and Data Management Center after more than 20 years of service effective May 1, 2023. She began as Program Manager in 2002 and was promoted to Director in 2011 with the merger of three groups into the Alliance. In total, Ms. Darcy has 38 years of experience working with multiple sponsors and managing relationships with large memberships and affiliates. She has led numerous operational changes that improved quality and reduced efforts for memberships and internal operations, including early closure and termination processes. In addition, she has help facilitate efforts to transition from paper base forms and data collection efforts to electronic data capture and storage. As a subject expert in

clinical research operations, she also helped cultivate and maintain strong working relationships between the memberships and the research base.

**Committee Appointments** 



Daniel J. George, MD



Gregory A. Masters, MD

**Daniel J. George, MD**, has been appointed Interim Chair of the Alliance Genitourinary Committee, effective February 2023. Dr. George replaces **Michael J. Morris, MD**, Prostate Cancer Section Head in GU Oncology at the Memorial Sloan Kettering Cancer Center. Dr. Morris retired as Committee Chair after more than 10 years of distinguished service in January 2023.

Dr. George is a Professor of Medicine and Professor in Surgery at Duke University Medical Center. He oversees a clinical research team focused on developing therapy and improving care and outcomes for patients with urologic cancers, mostly prostate, kidney, and bladder cancer. His work involves both interventional trials with new and emerging therapies as well as diagnostic tests and markers of cancer biology, response, and outcome. With a particular interest in immuno-oncology agents as well as targeted therapy, his team is heavily invested in understanding ways to improve the cancer experience for patients, including many lifestyle interventions and supports.

**George A. Masters, MD**, has been appointed Chair of the Alliance Conflict of Interest Committee, effective March 2023. Dr. Masters replaces **James D**. **Bearden III, MD, FACP**, Vice President of Clinical Research for Spartanburg Regional Healthcare System, Managing Physician for Gibbs Cancer Center, and Director of the Bearden-Josey Center for Breast Health. Dr. Bearden retired as Committee Chair after more than 10 years of distinguished service in January 2023.

As a lung cancer specialist with the Delaware/Christiana Care NCI Community Oncology Research Program, Dr. Masters is a highly published expert who travels the country speaking to medical audiences on lung cancer. He also serves as a reviewer for many of the leading oncology clinical publications, including *Lancet, Journal of Clinical Oncology, Lung Cancer, Cancer, British Journal of Cancer,* and the *American Journal of Cancer*. He has received numerous professional honors and currently serves on the American Society of Clinical Oncology Clinical Practice Committee, on the Editorial Board of the Journal of Clinical Oncology, and as a member of the Professional Advisory Board for The Wellness Community in Delaware.



Michael A. Linden, MD, PhD

Michael A. Linden, MD, PhD, has been appointed Chair of the Alliance Pathology Committee, effective December 2022. Dr. Linden replaces **Eric D. Hsi, MD**, Chair and Professor of Pathology in the Department of Pathology at Wake Forest School of Medicine, and Pathology/Laboratory Medicine Enterprise Service Leader and Academic Chair at Wake Forest Baptist Health, Atrium Health. Dr. Hsi retired as Committee Chair after 10-plus years of distinguished service in November 2022.

Dr. Linden is the Director of Hematopathology and a Professor within the Department of Laboratory Medicine and Pathology at the University of Minnesota, Minneapolis, MN. An international expert in flow cytometry, Dr. Linden previously led programs through the College of American Pathologists to standardize the validation and reporting of flow cytometric minimal residual disease testing (MRD) for leukemia, lymphoma, and myeloma, as well as created new products to measure and compare flow cytometric analytical performance among labs. He has been a member of the Alliance Pathology Committee and Alliance Myeloma Committee since 2017. Dr. Linden research focuses on improving and creating new diagnostic approaches for patients with myeloma and other hematologic malignancies.



Jennifer Ligibel, MD



Y. Nancy You, MD, MHSc

**Jennifer Ligibel, MD,** and **Y. Nancy You, MD**, **MHSc**, have been appointed Vice-Chairs of the Alliance Prevention Committee, effective March 2023.

Dr. Ligibel is an Associate Professor of Medicine at Harvard Medical School, and Director of the Leonard P. Zakim Center for Integrative Therapies and Healthy Living and Director of the Center for Faculty Well-Being at the Dana-Farber Cancer Institute. Her research interests include the relationship between energy balance and breast cancer prognosis, the biological impact of exercise on the body, as well as the impact of diet and exercise on breast cancer prognosis. She is currently conducting a trial looking at the impact of exercise on insulin and numerous other fat-derived hormones in breast cancer survivors, as well as a project looking at the feasibility of home-based exercise in patients undergoing treatment for early-stage breast cancer.

Dr. You is a Professor in the Department of Colon and Rectal Surgery -Division of Surgery, Associate Medical Director of the Clinical Cancer Genetics Program, and Affiliate Faculty in the Clinical Cancer Genetics Program at the University of Texas MD Anderson Cancer Center. She performs both open and advanced minimally invasive surgery for colorectal cancer. Her clinical focus is personalized surgical care for colorectal cancer that is coordinated with multidisciplinary treatments, emphasizing sphincter-preservation, quality-of-life, and long-term cancer survivorship. Her research also centers on hereditary cancer predisposition syndromes and on colorectal cancer particularly that occurring before age 50.

# Special Recognition 2023 AACR Distinguished Public Service Award



Phyllis Pettit Nassi, MSW



Jane Perlmutter, PhD, MBA

The Alliance for Clinical Trials in Oncology, along with the Alliance Cancer Control Program and Alliance Patient Advocate Committee, recognizes and congratulates Alliance Patient Advocates **Phyllis Pettit Nassi, MSW**, and **Jane Perlmutter, PhD, MBA**, as recipients of the 2023 American Association of Cancer Research (AACR) Distinguished Public Service Award for Exceptional Leadership in Cancer Advocacy, which was presented during the AACR Annual Meeting 2023 Opening Ceremony on April 16 in Orlando, FL.

This award recognizes individuals whose extraordinary work has exemplified the AACR's mission to prevent and cure all cancers through research, education, communication, collaboration, science policy, advocacy, and funding for cancer research.

Ms. Pettit Nassi was recognized for her longstanding commitment as a patient advocate for American Indian Tribes across the Mountain West and beyond, and for an unwavering commitment to improving health literacy and clinical trial enrollment among American Indian populations. Her work has profoundly impacted tribal, rural, and frontier communities and improved quality of life and access to cancer care.

Dr. Perlmutter was recognized for her unparalleled leadership as a patient

advocate, including through the AACR's Scientist↔Survivor Program®; her dedication to improving the patient experience through innovative clinical trial designs, including ISPY2, TAPUR and the Alliance for Clinical Trials; and for efforts to ensure that the patient voice is included in research and trial design, accelerating patient access to new treatments and drastically improving their quality of life and overall survivorship.

"Ms. Pettit Nassi and Dr. Perlmutter's advocacy work has had a powerful impact on the lives of patients with cancer," said Margaret Foti, PhD, MD (hc), Chief Executive Officer of the AACR. "Phyllis has devoted her career to improving outreach to and clinical trial enrollment for American Indians, a greatly underserved patient population. Jane's important contributions to clinical trial design have helped ensure that clinical cancer research is inclusive and sensitive to patient issues. They have both served as dedicated mentors to other advocates, amplifying and strengthening the patient voice within the cancer research community. The AACR is immensely proud to honor them with these Distinguished Public Service Awards."

Read more about the award and recipients here.

## **Recently Activated Alliance Trials**

#### Alliance A092107 | Advanced Dedifferentiated Liposarcoma

"A randomized phase 2 trial with a safety lead-in to evaluate palbociclib versus palbociclib and cemiplimab for the treatment of advanced dedifferentiated liposarcoma"

**Matthew Ingham, MD**, of Columbia University, leads this phase II trial that compares the effect of treatment with palbociclib alone to treatment with palbociclib plus cemiplimab for treating patients with dedifferentiated liposarcoma that may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body (advanced). Palbociclib may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Cemiplimab is a monoclonal antibody that may interfere with the ability of cancer cells to grow and spread. The combination of these two drugs may be more effective in shrinking or stabilizing advanced dedifferentiated liposarcoma compared to palbociclib alone. The trial opened on March 24, 2023. To learn more, visit <u>CT.gov</u>.

Alliance A082101 | Sarcomatoid Mesothelioma

"Multimodality immunotherapy in sarcomatoid mesothelioma"

**Aaron Mansfield, MD**, of Mayo Clinic, leads this phase II trial that evaluates the safety and effectiveness of giving immunotherapy (nivolumab and ipilimumab) before surgery for controlling disease in patients with stage I-IIIa sarcomatoid mesothelioma. Immunotherapy with monoclonal antibodies, such as nivolumab and ipilimumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Giving immunotherapy before surgery may be more effective at controlling disease in patients with sarcomatoid mesothelioma than giving immunotherapy alone. The trial opened on March 14, 2023. To learn more, visit <u>CT.gov</u>.

#### Alliance A042001 | Acute Lymphoblastic Leukemia

"A randomized phase II study comparing inotuzumab plus chemotherapy versus standard chemotherapy in older adults with Philadelphia-chromosome-negative b-cell acute lymphoblastic leukemia"

**Marlise R. Luskin, MD, MSCE**, of Dana-Farber Cancer Institute, leads this phase II trial that compares the combination of inotuzumab ozogamicin and chemotherapy to the usual chemotherapy in treating patients with B-cell acute lymphoblastic leukemia or B-cell lymphoblastic lymphoma. Inotuzumab ozogamicin is a monoclonal antibody, called inotuzumab, linked to a drug, called CalichDMH. Inotuzumab is a form of targeted therapy because it attaches to specific molecules (receptors) on the surface of cancer cells, known as CD22 receptors, and delivers CalichDMH to kill them. Chemotherapy drugs work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving inotuzumab ozogamicin with chemotherapy may help shrink the cancer and stop it from returning. The trial opened on January 11, 2032. To learn more, visit <u>CT.gov</u>.

#### Alliance A022102 | Gastroesophageal Adenocarcinoma

"A randomized phase III trial of mFOLFIRINOX +/- nivolumab vs. FOLFOX +/- nivolumab for first-line treatment of metastatic HER2-negative gastroesophageal adenocarcinoma"

**Haeseong Park, MD, MPH,** of Dana-Farber Cancer Institute, leads this phase III trial that compares the effect of modified fluorouracil, leucovorin calcium, oxaliplatin, and irinotecan (mFOLFIRINOX) to modified fluorouracil, leucovorin calcium, and oxaliplatin (mFOLFOX) for the treatment of advanced, unresectable, or metastatic HER2 negative esophageal, gastroesophageal junction, and gastric adenocarcinoma. The usual approach for patients is treatment with FOLFOX chemotherapy. Chemotherapy drugs work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Fluorouracil stops cells from making DNA and it may kill tumor cells. Leucovorin is used with fluorouracil to enhance the effects of the drug. Oxaliplatin works by killing, stopping, or slowing the growth of tumor cells. Some patients also receive an immunotherapy drug, nivolumab, in addition to FOLFOX chemotherapy. Immunotherapy may induce changes in body's immune system and may interfere with the ability of tumor cells to grow and spread. Irinotecan blocks certain enzymes needed for cell division and DNA repair, and it may kill tumor cells. Adding irinotecan to the FOLFOX regimen could shrink the cancer and extend the life of patients with advanced gastroesophageal cancers. The trial opened on January 11, 2023. To learn more, visit <u>CT.gov</u>.

#### Alliance A022101 | Metastatic Colorectal Cancer (ERASur)

"A pragmatic randomized phase III trial evaluating total ablative therapy for patients with limited metastatic colorectal cancer: evaluating radiation, ablation, and surgery (ERASur)"

Eric D. Miller, MD, PhD, of Ohio State University Comprehensive Cancer Center, leads this phase III trial that compares total ablative therapy and usual systemic therapy to usual systemic therapy alone in treating patients with colorectal cancer that has spread to up to four body sites (limited metastatic). The usual approach for patients who are not participating in a study is treatment with intravenous (IV) (through a vein) and/or oral medications (systemic therapy) to help stop the cancer sites from getting larger and the spread of the cancer to additional body sites. Ablative means that the intention of the local treatment is to eliminate the cancer at that metastatic site. The ablative local therapy will consist of very focused, intensive radiotherapy called stereotactic ablative radiotherapy (SABR) with or without surgical resection and/or microwave ablation, which is a procedure where a needle is temporarily inserted in the tumor and heat is used to destroy the cancer cells. SABR, surgical resection, and microwave ablation have been tested for safety, but it is not scientifically proven that the addition of these treatments is beneficial for every patient's stage of cancer. The addition of ablative local therapy to all known metastatic sites to the usual approach of systemic therapy could shrink or remove the tumor(s) or prevent the tumor(s) from returning. The trial opened on January 10, 2023. To learn more, visit CT.gov.

## **Alliance Trial Results in the News**

• Women with multiple tumors in one breast may be able to avoid a

mastectomy

- Pausing long-term breast cancer therapy to become pregnant
  <u>appears to be safe</u>
- Less lung tissue removal needed for early-stage cancer, study finds
- Lobar or sublobar resection for peripheral stage ia non-small-cell lung cancer
- Lung-sparing surgery is effective for some with early-stage lung cancer
- <u>Can one blood test transform cancer screening?</u>
- Outcomes of older adults with AML Treated in community versus academic centers: An analysis of Alliance trials
- Outcome prediction by the 2022 European LeukemiaNet genetic-risk classification for adults with acute myeloid leukemia: an Alliance study
- Lessons learned from conducting the first cancer care delivery trial in the Alliance for Clinical Trials in Oncology (Alliance A191402CD)
- Local-regional recurrence after neoadjuvant endocrine therapy: Data from ACOSOG Z1031 (Alliance), a randomized phase 2 neoadjuvant comparison between letrozole, anastrozole, and exemestane for postmenopausal women with estrogen receptorpositive clinical stage 2 or 3 breast cancer

## 2023 Alliance Spring Virtual Group Meeting Convenes This Week





The 2023 Alliance Spring Virtual Group Meeting will convene this week for four days, beginning May 3. The meeting will host a variety of scientific and administrative sessions led by distinguished oncology researchers, clinical trial specialists, and administrators from across the country. It will showcase novel and innovative cancer control, prevention, and treatment trials conducted by investigators through a multidisciplinary academic and community research network, as part of the NCI National Clinical Trials Network (NCTN) and Community Oncology Research Program (NCORP). Read more.

