INTRODUCING THE ECOG-ACRIN ADVOCATE NEWSLETTER

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In the August issue of the ECOG-ACRIN (EA) Newsletter, we highlighted the work of EA’s Cancer Research Advocates Committee (CRAC), a group vital to our organization. We noted the critical role this Committee plays in advancing ECOG-ACRIN’s mission to achieve research advances in all aspects of cancer care. The CRAC was formed to help bridge the gap between researchers and patients; to ensure the patient voice is represented at every stage of EA clinical trial design and implementation. As mentioned in the EA Newsletter, the CRAC’s efforts to date have been fruitful, in some cases leading to changes in therapy approaches.

To complement and expand the work of the Cancer Research Advocates Committee, we are launching this ECOG-ACRIN Advocate Newsletter to connect with the broader advocacy community, and encourage interaction, feedback, and dialogue. In each issue, we plan to feature one recently activated trial, one ongoing trial, and one trial that has published results. Occasionally, we will also include polls or design questions to help inform upcoming projects. We look forward to engaging with you on these topics, and applying what we learn to our research efforts.

The three trials in this issue span different cancer types and research disciplines. Our recently launched trial, EAZ171, aims to address an important survivorship issue, neuropathy, in African American women diagnosed with breast cancer. Our ongoing trial, EA1151/TMIST, is a breast cancer screening study that will lead to personalized screening for women. Finally, the results of leukemia trial E1912 were recently published in The New England Journal of Medicine, and established a new standard of care for the initial treatment of chronic lymphocytic leukemia (CLL). We hope you enjoy learning about these studies, and urge you share this newsletter with others. Please also share your thoughts and feedback with us at support@ecog-acrin.org.

RECENTLY ACTIVATED: EAZ171 – PROSPECTIVE VALIDATION TRIAL OF TAXANE THERAPY (DOCETAXEL OR WEEKLY PACLITAXEL) AND RISK OF CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY IN AFRICAN AMERICAN WOMEN

The American Society of Clinical Oncology considers neuropathy caused by chemotherapy to be one of the three most important survivorship issues impacting cancer patients. Symptoms of neuropathy most often appear in the hands and feet and include numbness, tingling, pain, muscle weakness, and sensitivity to temperature. This discomfort can be so great that doctors lower or even stop chemotherapy doses in their patients. When this happens, cancer is more likely to come back (recur).

Recent research shows patients of African ancestry have a much higher risk of experiencing side effects from chemotherapy, especially neuropathy, and thus have a higher risk of discontinuing treatment. This results in increased recurrence and worse survival rates in Black patients compared with White patients. EAZ171, led by Bryan P. Schneider, MD of Indiana University School of Medicine, aims to improve outcomes for Black women with breast cancer by:

1) Determining which women are most at-risk for neuropathy based on their DNA, and

2) Determining which regularly prescribed chemotherapy treatment, docetaxel or paclitaxel, will result in less neuropathy.
Through this work, researchers hope to definitively conclude which treatment is better, and less likely to cause neuropathy, for women of African ancestry. They also hope to learn more about why Black women, specifically, are more susceptible to neuropathy.

Learn more about EAZ171 on the ECOG-ACRIN website.

**ONGOING: EA1151/TMIST – TOMOSYNTHESIS MAMMOGRAPHIC IMAGING SCREENING TRIAL**

The Tomosynthesis Mammographic Imaging Screening Trial (TMIST) is a breast cancer screening study that launched in July 2017. It is the first randomized controlled trial that seeks to identify women in which digital breast tomosynthesis (DBT or 3D mammography) may outperform digital (2D) mammography in reducing advanced breast cancer development. Right now, researchers simply do not know whether one method is better than the other at finding life-threatening breast cancers early. Although tomosynthesis (3D) is the newer technology, and thus more sensitive, investigators want to confirm this sensitivity actually benefits women and improves their probability of living longer.

Furthermore, today’s screening strategy entails a one-size-fits-all approach based primarily on age. All women undergo the same procedure, regardless of risk level. The data collected through TMIST will lead to better, individualized screening strategies based on each woman’s risk factors. Some women may benefit from less screening, while others may require more intensive screening.

“Wouldn’t it be better if we could adapt based on all [our] new knowledge and provide individualized recommendations?” asks Study Chair Etta D. Pisano, MD of Beth Israel Deaconess Medical Center, Harvard Medical School, and the American College of Radiology. “We could develop a tool that allows us to tell individual women, ‘Given your risk factors, your particular circumstances, and your genetics, here is what we recommend.’”

Learn more about TMIST, currently enrolling healthy women ages 45 – 74 throughout North America.

**TRIAL RESULTS: E1912 – IBRUTINIB AND RITUXIMAB COMPARED WITH FLUDARABINE PHOSPHATE, CYCLOPHOSPHAMIDE, AND RITUXIMAB IN TREATING PATIENTS WITH UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA OR SMALL LYMPHOCYTIC LYMPHOMA**

Final results from trial E1912 appeared in the New England Journal of Medicine in early August. The study, led by Tait Shanafelt, MD of Stanford Medicine, found the combination of ibrutinib plus rituximab was superior to standard treatment for patients age 70 and younger with previously untreated chronic lymphocytic leukemia (CLL). The combination led to improvements in both progression-free survival (the length of time patients live before their disease worsens) and overall survival. Additionally, patients who received ibrutinib-rituximab were less likely to experience serious side effects than those who received standard treatment.

“These results are practice-changing and immediately establish ibrutinib and rituximab as the new standard of care for the initial treatment of CLL in patients age 70 and younger,” said Dr. Shanafelt.

The findings were initially presented as a late-breaking abstract at the American Society of Hematology (ASH) Annual Meeting in December 2018. Results from another NCI-supported trial on ibrutinib in patients with CLL, , led by the Alliance for Clinical Trials in Oncology, were also presented at the ASH meeting. Trial A041202 demonstrated that ibrutinib produces superior progression-free survival compared with standard chemoimmunotherapy (bendamustine plus rituximab) in previously untreated patients with CLL who are age 65 and older. The study found that adding rituximab to ibrutinib did not improve progression-free survival beyond ibrutinib alone.

Read the press release to learn more.