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NEWS RELEASE

New *e3* clinical trial tests drug to delay recurrence of high-risk breast cancer

The Evaluating Everolimus with Endocrine Therapy (e3) study asks whether everolimus – recently approved for treating metastatic disease – can help make standard endocrine therapy more effective at preventing the spread or recurrence of earlier stage breast cancer.

PORTLAND, ORE. – A newly opened, nationwide research study will test whether adding the drug everolimus (Afinitor) to standard adjuvant hormone therapy can delay cancer's spread or recurrence in patients being treated for high-risk breast cancer.

The National Cancer Institute (NCI)-sponsored e3 Breast Cancer Study (Evaluating Everolimus with Endocrine therapy), looks to enroll 3,500 women and men being treated for hormone receptor-positive breast cancer that, while it has not yet spread to distant sites in the body, is considered at high risk of doing so.

After completing surgery, chemotherapy and, if needed, radiation therapy, all patients on this phase III trial will be treated with long-term endocrine therapy (also known as hormone therapy). One half of the group will be randomly assigned to also get a daily dose of everolimus for one year. The rest of the volunteers will take a matched daily placebo for one year. Neither doctor nor patient will know whether the patient is getting the drug or the placebo.

Investigators are looking to learn whether the combination of everolimus and endocrine therapy will lengthen patients' invasive disease-free survival time when compared to endocrine therapy alone. They will also assess the impact of everolimus on the quality of life of these breast cancer survivors.

Everolimus was approved by the United States Food and Drug Administration (FDA) in the summer of 2012 for treating metastatic breast cancer. Evidence weighed by the FDA reviewers included results from the BOLERO-2 clinical trial, which found that adding the drug to the endocrine therapy drug examestane more than doubled the average time to disease progression for patients with hormone receptor-positive breast cancer that had metastasized.

"FDA approval of everolimus for HR-positive metastatic cancer was based on solid evidence that the drug can help extend the time to breast cancer progression, likely by restoring endocrine sensitivity," says study chair Mariana Chavez-MacGregor, M.D., of the MD Anderson Cancer Center in Houston, Texas, and SWOG.

"Our hypothesis in the e3 trial is that adding everolimus to standard adjuvant endocrine therapy in patients whose cancer has *not* yet spread will extend the effectiveness of that therapy, and will delay or prevent recurrence or metastasis in high-risk patients."

Estrogen is a hormone that can promote tumor cell growth in patients with hormone receptor-positive breast cancer. Endocrine therapy uses drugs to reduce the amount of estrogen the body makes or to block the ability of the body's cells to use estrogen, robbing cancer cells of this important driver. But in most patients, cancer eventually evolves to become resistant to such treatment. Everolimus may reverse this resistance, making cancer cells sensitive to endocrine therapy once again.

While determining whether everolimus adds to endocrine therapy's effectiveness, e3 researchers will also study what impact the drug may have on the quality of life of patients who may still be recovering from the effects of their earlier surgery, chemotherapy, and/or radiation therapy.

"We need to understand to what extent any disease-free survival benefits patients might see from adding everolimus to therapy are counterbalanced by increased fatigue, reduced functioning, or other side effects they might experience while taking the medication," says Patricia Ganz, M.D., of the Jonsson Comprehensive Cancer Center at the University of California, Los Angeles, and NSABP. Ganz is directing the quality-of-life portion of the e3 study.

Also known as S1207, the e3 trial is being led by the SWOG and NSABP cancer research cooperative groups within the NCI's National Clinical Trials Network. Starting in late 2013, it opened to enrollment at hundreds of treatment sites across the United States and at cancer centers in several other countries.

For more information about the e3 trial, including a list of sites that are now enrolling to the study, visit clinicaltrials.gov/ct2/show/NCT01674140 or swog.org/patients/e3.

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The **NSABP** Foundation, Inc., a non-profit corporation, is headquartered in Pittsburgh, Pennsylvania. Over its 50 year history, the NSABP has designed and conducted clinical trials that have changed the way colorectal and breast cancers are treated. NSABP breast cancer prevention studies have provided high risk women with chemoprevention options. With research sites at nearly 1,000 major medical centers, university hospitals, large oncology practice groups, and health maintenance organizations nationally and internationally, the NSABP has enrolled more than 110,000 women and men in clinical trials in breast and colorectal cancer. More than 7,000 physicians, nurses, and other medical professionals conduct NSABP treatment and prevention trials.

SWOG is a cancer research cooperative group that designs and conducts multidisciplinary clinical trials to improve the practice of medicine in preventing, detecting, and treating cancer, and to enhance the quality of life for cancer survivors. The more than 4,000 researchers in the group's network practice at more than 650 institutions nationwide, including 24 of the National Cancer Institute (NCI)-designated cancer centers, as well as cancer centers in almost a dozen other countries. Formerly the Southwest Oncology Group, SWOG is supported primarily through NCI research grant funding. The group is headquartered at the Oregon Health & Science University in Portland, Oregon, (503-494-5586), has an operations office in San Antonio, Texas, and has a statistical center in Seattle, Washington. Learn more at swog.org.