

Month Day, 2019

Dear Research Participant (or name):

You are receiving this letter because you are currently participating in the research study called Alliance A011203, “A randomized phase II trial of tamoxifen versus Z-endoxifen HCL in postmenopausal women with metastatic estrogen receptor positive, HER2 negative breast cancer.” We now have enough information to share the study results with you.

### **WHY IS THIS RESEARCH STUDY BEING DONE?**

This research study is being done to test two different treatments, Z-endoxifen HCL and tamoxifen, for postmenopausal women with estrogen receptor positive and HER2 negative breast cancer that no longer responds to aromatase inhibitors (anti-estrogen therapy) and has spread in the breast, or to other parts of your body. This study is designed to see if one of these two treatments will help people with breast cancer live longer without disease progression than the other, and to compare any good and bad effects of the two treatments.

### **WHAT HAS HAPPENED?**

A group of cancer research specialists including patient advocates, not directly involved in the study, regularly look at the results from all participants who joined this research study. They look to see if enough information is available to answer the study question about the best treatment for participants in your situation.

These experts have just informed us of a finding that is important to the participants being treated on this study.

- The participants treated with Z-endoxifen HCL did not do better than participants treated with tamoxifen. Some participants whose tumors grew on tamoxifen and were switched to Z-endoxifen HCL received benefit.

### **ASK YOUR DOCTOR.**

You can continue participation in the study and continue to take study treatment as long as your cancer is not getting worse or you are not experiencing intolerable side effects, according to the original treatment

plan of the study. If you are taking Z-endoxifen HCL you may continue Z-endoxifen HCL after consulting with your doctor.

For patients who continue taking Z-endoxifen HCL, the medication will continue to be provided free-of-charge by the National Cancer Institute. If you want to stop the study treatment, you and your doctor together will decide which further treatment you will receive going forward. Choices regarding further treatment will be an individual medical decision between you and your doctor.

As in any research study, you may always decide to stop participating at any time by informing your study doctor of your wishes. Regardless of the treatment option that you choose, we will continue to collect information about your progress so that we can get as much valuable information as possible from this study. This information will help us to continue to understand and treat this disease.

You have been a very important part of this study, and we thank you for participating. Even though this study does not show that Z-endoxifen HCL is better at increasing the time without disease progression compared to tamoxifen, this trial has been an important effort to understand how we may best make progress fighting breast cancer in the future. We will use lessons learned from this trial to develop other studies and approaches to improve the lives of patients living with breast cancer. We greatly appreciate your participation in A011203.