Welcome to the first issue of the PROMISE clinical trial newsletter!

The goal of this quarterly newsletter is to provide women with advanced breast cancer with information regarding the Mayo Clinic PROMISE study as well as next steps to take if they would like to consider participation in this clinical trial.

About the PROMISE Study

The goal of the PROMISE study is to learn more about why hormone-receptor positive breast cancers become resistant to treatments and to develop better treatment options for these patients. We will look for genetic changes in each participant’s cancer over the course of their treatment in both cancer tissue and blood. We will compare the genetic material from the tumor with the genetic material found in the blood for similarities and differences. This information may help us to identify genetic changes which may help us determine why some patients respond to treatment and other patients do not. This information will hopefully help us develop new, more effective and better tolerated treatments for patients with estrogen-receptor positive, HER2-negative metastatic breast cancer. YouTube Link
All patients on the study will receive the results of the tumor and blood genetic sequencing at no cost. This information may be used to help you and your doctor decide on your future treatment options.

Am I a candidate for this study?

If you can answer yes to all of the following statements, this study could be a good option for you.

1. Female over 18
2. Breast cancer which cannot be removed by surgery
3. Hormone receptor positive breast cancer
4. HER2-negative breast cancer
5. About to start treatment with palbociclib (Ibrance) and fulvestrant (Faslodex) or palbociclib (Ibrance) and letrozole (Femara)

What does the study involve?

To participate in PROMISE, each patient needs to meet with an Oncologist at Mayo Clinic in Minnesota, Florida or Arizona. First, there is a screening period, where a tumor biopsy will be collected to confirm that your cancer is estrogen receptor positive and HER2-negative. If it is, and you decide to join the study, you will then start your treatment. Blood, urine, saliva and stool samples are also collected at this time. The biopsy and blood tests are repeated after two months, and again when your cancer grows on treatment. These tests will help us to understand why the tumors were, or became, resistant to Ibrance and the anti-hormonal therapies. The stool sample is collected to help us understand whether changes in bacteria in the gut, e.g. the microbiome, influence how well, or poorly, patient’s cancers respond to Ibrance and antihormonal treatment. You can have your cancer treatment at Mayo Clinic or with a doctor closer to home. You will need to come back to Mayo for tests every 2-3 months until Ibrance is found to no longer be working.

What are the risks/benefits?

All patients receive treatment with anti-hormonal therapies and Ibrance, which are approved by the Food and Drug Authority (FDA) for breast cancer, so the study is low risk. The results of the genetic testing (of both the tumor and the patient) may be used to help you and your oncologist to select the next cancer treatment after your cancer grows on anti-hormonal treatment and Ibrance. This genetic testing will provided to you at no cost.

If you are interested in participating in PROMISE, please talk to your doctor. You can find out more information about this study by searching “NCT03281902” on the ClinicalTrials.Gov website, or at this link.
You may also contact our study team at the following sites:

Mayo Clinic Rochester:
Jackie Chonis, e-mail: chonis.jacquelyn@mayo.edu; phone: 507-284-1887

Mayo Clinic Florida:
Jessica Schlesinger, e-mail: Schllesinger.Jessica@mayo.edu; phone: 904-953-3643

Mayo Clinic Arizona:
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Thank you for considering participation in this research study!

PROMISE Study Team Member Spotlight (September 2019):
Dr. Ciara O’Sullivan
PROMISE Study Lead Researcher

Why is the PROMISE study important?  PROMISE represents a unique opportunity for doctors and patients to learn more about advanced breast cancer, with the goal of personalizing therapy for each patient and developing more effective treatments.

What I enjoy doing in my spare time:  Spending time with family and friends in the US and in my native Ireland, trying new restaurants, reading and traveling.

The ultimate goal is to individualize breast cancer treatment, enabling physicians to provide the best care to each patient.

The PROMISE study is funded by the Mayo Clinic Center for Individualized Medicine and also by the American Society of Clinical Oncology and Conquer Cancer Foundation.