NRG Oncology Clinical Trial: NRG-GI004

Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer

About the trial
NRG-GI004 is a clinical trial that is studying three treatment options for patients with colorectal cancer that has spread to other parts of their body (metastatic). This study is specifically for patients who have a particular type of colorectal cancer called “MSI-high” or “DNA repair deficient”. This can usually be known by doing a specific test on a small piece of the cancer that was used to diagnose the colorectal cancer. For patients with such a type of colorectal cancer, doctors know that new medicines that can help the patient's own immune system attack the cancer, can be of benefit after usual chemotherapy stops working. This study is trying to answer the question of which treatment is best to start with. Therefore, patients in this study will be randomly assigned to receive one of three treatment options: the usual treatment for this type of cancer, the experimental drug atezolizumab, or the usual treatment combined with the experimental drug atezolizumab.

If you agree to take part in this study, you will also have the opportunity to participate in an optional sample collection for possible future studies. An additional sample of tumor tissue from your previous biopsy or surgery and blood samples will be collected if you choose to participate in the sample collection. Researchers use these samples to help them learn more about your cancer, using blood and tissue to find new ways to prevent, detect, treat, or cure cancer.

The COMMIT Study: Comparing the Drug Atezolizumab to the Usual Treatment Approach for Colon Cancer

About NRG Oncology

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of people with cancer. As one of the five research groups in the National Cancer Institute’s (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology’s extensive research organization comprises multidisciplinary investigators, including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians, and encompasses more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI.

To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org
What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
Men or women who have colorectal cancer that is known to have a genetic change, has spread to other parts of your body (metastatic), and you have not yet received treatment for metastatic colorectal cancer.

Am I required to be in this study?
No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible treatments?
All patients will be randomly assigned to one of three groups in the study. Group 1 will receive chemotherapy and bevacizumab. Group 2 will receive the study drug atezolizumab alone. Group three will receive a chemotherapy and bevacizumab combined with the study drug atezolizumab. The type of chemotherapy you will receive is a combination called FOLFOX which includes 5-fluorouracil (5-FU), leucovorin, and oxaliplatin.

How long will I be in this study?
If you are in Group 1 or Group 3, you will receive 5-FU, leucovorin, and bevacizumab for as long as you continue to benefit or as long as your doctors think it is safe to keep you on therapy. You will receive oxaliplatin for up to a total of 10 cycles.

If you are in Group 2 or Group 3, you will receive atezolizumab for about 2 years.

If you stop study treatment for any reason, your study doctor will see you about 1 month after you stop to check for any side effects that you may be having. If your cancer has not progressed (grown) at the time you stop study treatment, you will continue to have scans until your cancer grows or until you begin another treatment for your cancer. After that, the researchers who are conducting this study would like to know how you are doing about every 6 months from the time you stop study therapy through about 5 years from when you joined the study. This can be done at a visit to your study doctor or by a phone call from your study team.

Are there side effects?
FOLFOX, bevacizumab, and atezolizumab may cause side effects. Your doctor will review all of the potential side effects with you. You are encouraged to tell your doctor about any side effects during the study so that they may be treated and so that potential adjustments to the study drugs may be made.

More Information
Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer. You may also call: 1-(800)-4-CANCER (1-800-422-6237)