WHY SHOULD I PARTICIPATE IN THIS STUDY?

Participants may:

- Try an oral investigational drug to see if it reduces the signs and symptoms of ulcerative colitis (UC)
- Help further the understanding of UC and how an oral investigational drug may affect sperm production
- Receive the study drug and monitoring from a local study doctor at no cost
- Be eligible to participate in a long-term extension study

COULD I QUALIFY FOR MANTA?

Participants must:

- Be diagnosed with moderate to severe UC and have active disease
- Be a biological male 25 to 55 years of age

The study doctor will discuss other eligibility criteria with you.

You don't need health insurance or referrals to participate. The study drugs will be provided at no cost. Drugs you are currently taking for your UC or other conditions will not be paid for by the study.

MANTA

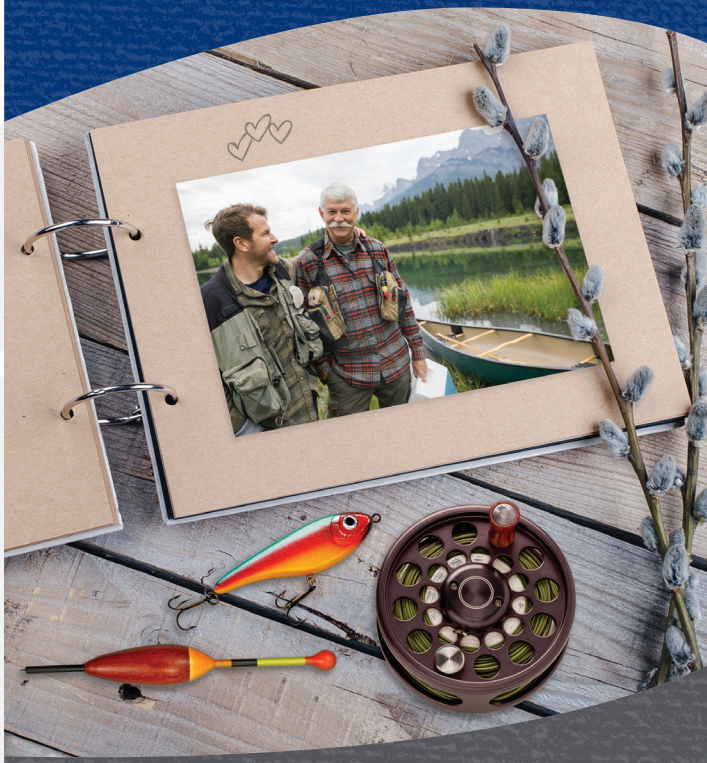
FOR MORE INFORMATION, CONTACT:

Filgotinib is an investigational drug whose safety and efficacy have not been established.

GS-US-418-4279_Rev8_07MAR2018

Does ULCERATIVE COLITIS

Have You Tied Up in Knots? Consider this Research Study for Men.



The MANTA Study

Our medical team is evaluating an oral investigational drug called filgotinib for people with moderate to severe ulcerative colitis and any impact it may have on a man's ability to produce sperm. Having a better understanding on how filgotinib affects sperm production will help determine whether this treatment is safe and can potentially help people with ulcerative colitis who are not responding well to currently available medications.

WHAT IS THIS CLINICAL RESEARCH STUDY ABOUT?

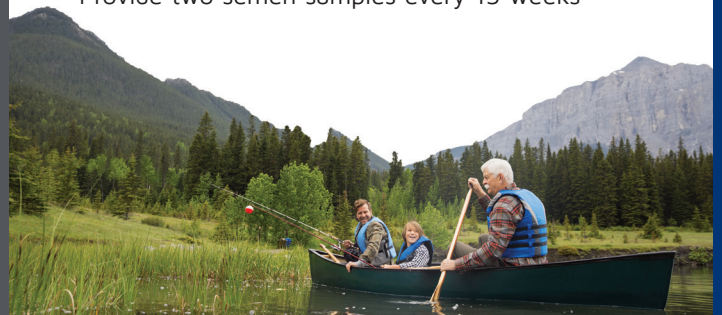
The MANTA study is evaluating filgotinib. This investigational drug is a "JAK1 inhibitor" that is taken as a pill once a day. JAK1 is a protein inside certain cells, including immune cells, which may stimulate their activity. When these immune cells are overactive, they can cause inflammation and trigger symptoms such as abdominal pain, diarrhea, and bloody stools. This research study is one of a series of studies that will help determine the safety of filgotinib in UC patients. An important aspect of clinical studies is determining what side effects may occur while taking the medication. This is a safety study that will determine whether filgotinib has any effect on sperm production (by looking at male hormones in the blood and sperm in semen samples). Men who qualify for the study and participate may have the opportunity to receive filgotinib.

WHAT DOES THE STUDY INVOLVE?

- The study will evaluate the study drug's effect on UC patients' sperm.
- The study doctor will explain the study to you and answer all of your questions. You will review and sign an informed consent form that explains the study in detail, including the potential risks and benefits of participation. A screening visit will then occur to see if your condition is a good fit for the study. If you qualify, you will be enrolled and you will:
  - Have 7 study clinic visits about 2 to 7 weeks apart.
  - Provide two semen samples at screening, two at week 13, and two at week 26 to determine if the study drug had any effect on sperm count.
  - Be randomly assigned (like the flip of a coin) and have a 50 percent chance of receiving the study drug or a placebo (looks like the study drug but contains no active ingredient) for up to 26 weeks. Neither you nor the study doctor will know which you are taking.
  - At week 13, if your UC symptoms haven't improved enough, and if you continue to qualify, you will stop the assigned study drug (which may be either filgotinib or placebo) and begin to take open-label filgotinib (you will no longer be blinded to your treatment).
  - If a 50 percent or higher decrease in sperm concentration is detected at week 13, you will enter the monitoring phase, stop the study medication, and resume standard of care treatment (like what you were taking before joining the study). You will continue to provide semen specimens every 13 weeks and be monitored for up to one year or until your sperm concentration returns to a baseline level, whichever is sooner.
- At week 26, if you qualify, you can choose to enroll in a long-term extension (LTE study) for up to 195 weeks and continue to receive the study drug or open-label filgotinib if you stopped blinded treatment at Week 13. You will continue to provide semen samples every 13 weeks.
- If a 50 percent or higher decrease in sperm concentration is detected at week 26, you will enter the monitoring phase as described above, rather than the LTE.
- If you do not qualify or choose not to take part in the LTE, you will have an end of treatment visit and a follow-up visit 30 days after the last dose of study drug.

WHAT WILL I BE ASKED TO DO?

- Attend all study appointments
- Give accurate information about your medical history, medications, and medical condition
- Take the study drug as instructed
- Provide two semen samples every 13 weeks



AFTER THE STUDY

- Participants who complete the MANTA study may have the opportunity to enroll in a long-term extension study.

WHAT ARE CLINICAL STUDIES?

Clinical research studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases and conditions. Studies, such as this one, are carefully supervised and done before an investigational drug is made available to the public. They are performed according to government regulations, which help protect the safety and rights of study participants. Studies are designed to make sure participants are monitored closely so if any side effects occur, they will be caught early and the investigational medicine can be modified or stopped as needed. Participation is completely voluntary and if you decide to participate, you can choose to leave the study at any time for any reason.

THE PURPOSE OF CLINICAL RESEARCH IS TO:

1. Answer specific health questions
2. Evaluate the safety and effectiveness of investigational drugs and devices
3. Discover new ways to improve health