WHAT CAN I EXPECT IF I JOIN THE STUDY?

If you qualify and choose to join the study and sign the informed consent form, you will be asked to attend 2 screening visits with the study doctor. At these visits, you will undergo tests and procedures to determine if you are a good match for continuing in the study.

- If you join the study, you'll be in it for about 10–12 weeks, with an option to participate in an open-label study for up to 1 year.
- You will be randomly assigned to 1 of 2 treatment groups. This means you may either receive a placebo (contains no active medicine) or the investigational medicine.
- Neither you nor the study team will know which treatment group you are in.
- Qualified patients may receive study-related medical care and investigational medication at no cost. The study will not pay for other medical care or current medication(s) needed to support your daily health care routine.

CAN I CHANGE MY MIND?

Yes. You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

For more information about this clinical research study, contact:

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RESEARCH STUDY

IRB Approved at the
Protocol Level
Jul 20, 2020

A Clinical Study to Evaluate an Investigational Medicine in Adults with Depression is Now Enrolling.

janssen

Janssen Research & Development, LLC
Patient Brochure, 25 Mar 2020 [V01 USA(en)]

Evaluating Investigational Medication through Clinical Research

WHAT IS A CLINICAL RESEARCH STUDY?

A clinical trial, also called a clinical research study, is a carefully designed scientific evaluation of an investigational medication or treatment. Clinical trials are conducted by doctors and researchers.

WHY IS CLINICAL RESEARCH IMPORTANT?

Clinical research helps doctors and scientists determine if an investigational medicine or therapies are safe and/or effective for use in humans to potentially treat a condition, disease or disorder. Clinical studies often require large number of volunteers to participate in a single study, sometimes thousands are needed to obtain reliable information.

WHAT IS INFORMED CONSENT?

"Informed Consent" is a process of information exchange before an adult agrees to participate in research. Potential research participants will be asked to read and sign an informed consent document, but will also be given instructions, verbally and in writing, question/answer sessions and other reading materials to ensure the potential study participant's understanding and willingness to voluntarily enroll in the research.

So before you agree to volunteer for the study, the study doctor or staff is required to explain all the details of the study, which will include the risks and benefits, and address your questions. After all of your questions have been answered, and if you wish to participate, then you will sign a document called the informed consent form to ensure:

- You agree to volunteer.
- You understand the study, including the study procedures, risks and potential side effects of the study medication.
- You understand that you can leave the study at any time, for any reason.

If you don't understand what is expected of you or the document, you should continue to ask questions and talk with the study doctor, your family or others that you trust, until you feel you understand.

PURPOSE OF THE STUDY

The purpose of this clinical research study is to determine the safety and effectiveness of an investigational medicine. This investigational medicine is being evaluated in people with depression.

AM I ELIGIBLE?

You may be able to participate in this study if you:

- are 18–74 years of age
- have been diagnosed with depression
- have taken antidepressants in the past that did not work well for you
- are currently taking an antidepressant medication but still have symptoms of depression.

Additional eligibility criteria will be assessed by the study doctor or staff during the screening process prior to being enrolled in the study and receiving any investigational medicine. Not all individuals may qualify to participate in the research.