Consider the COMP 006 Study of a New Investigational Approach for Treatment-Resistant Depression

Many people who receive antidepressant treatment for their depression do not get an adequate response to these treatments. This is sometimes referred to as treatment-resistant depression, or TRD.

This study will explore whether an investigational medicine, COMP360, together with psychological support, is an effective treatment for people who have not been helped by prior treatments for their depression.

Please speak with a study team member to learn more about the COMP 006 study.

COMP 006

About Clinical Studies

A clinical research study (sometimes called a clinical trial) is carefully supervised research that is done before a study drug or other investigational product is made available to the public.

- Clinical studies follow specific rules to protect the rights, safety, well-being, and confidentiality of study participants
- The results help government regulators decide if a medication or product is safe and should be made available to patients
- Clinical studies are the only way to develop new medical treatments to improve patient care

Participation in the COMP 006 clinical research study is completely voluntary. If you decide not to participate, it will not affect your medical care now or in the future. You may withdraw your consent and leave a study at any time.

For more information about the COMP 006 study, please contact:

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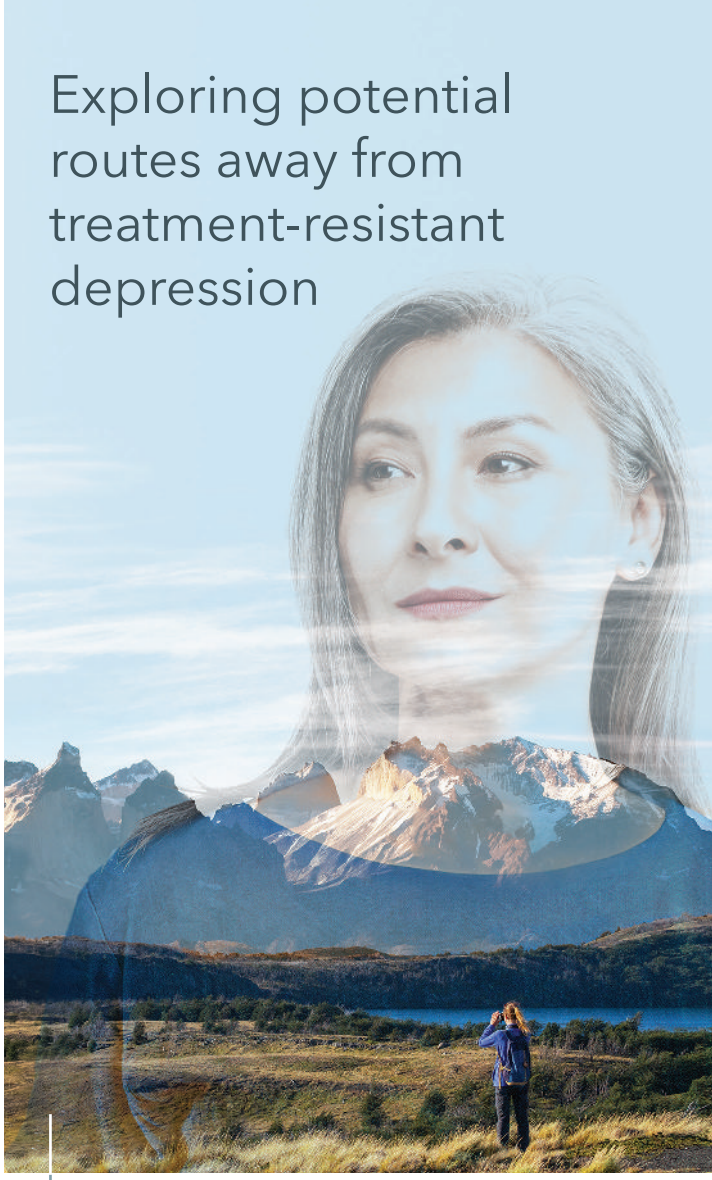
www.comp006study.com

COMP 006 COMPASSION

COMP 006 Brochure_V3.0_06MAR2023

Exploring potential routes away from treatment-resistant depression



Introducing the COMP 006 Study

Learn more about a study looking at a new investigational treatment approach for treatment-resistant depression using an investigational medicine alongside psychological support.

COMP 006 COMPASSION

About the COMP 006 Study

The COMP 006 study is trying to find out whether an investigational medicine, given with psychological support, can improve depressive symptoms for those who have treatment-resistant depression (TRD).

The study will compare the efficacy, safety and tolerability of three different doses of the active investigational medicine alongside psychological support.

All participants will receive one of three doses of COMP360 during the study. Some participants may be offered additional treatment sessions, depending on the results of their previous session.

Everyone in the study will have to stop taking any medicines that are prohibited by the study rules, including antidepressants.

Study Duration

The COMP 006 study lasts up to 62 weeks, made up of a screening period of 3–10 weeks and a treatment and follow-up period that includes three parts (Parts A, B, and C). Part A includes 2 treatment sessions with COMP360 and a 9-week follow up period. During Part B, eligible participants will be re-treated with COMP360 and be followed for 17 weeks. During Part C, eligible participants will receive treatment with COMP360 and be followed for a further 26 weeks. If you join the study, neither you nor the study doctors will know which you are going to receive during Part A and Part B because the decision is made randomly by a computer and is not revealed to anyone. During Part C you will know what dose of COMP360 you received.

The study treatment visits will take between 7–8 hours and includes time for some pre- and post-treatment assessments.

Participants can be accompanied by a family member/friend to the study treatment session who can either travel back home or to their hotel (if staying overnight) with them afterwards.

Participants are asked to remain off antidepressant treatments during Part A. If they return to antidepressant treatments during the study, there may be limitations on whether they can be re-treated with COMP360 later in the study. All participants who return to antidepressant treatment will be followed up until the end of the study.

Who Can Participate?

You may be eligible to participate in the COMP 006 study if you:

- Are 18 years of age or older
- Have been diagnosed with major depression (single or recurrent episodes); if a single episode, it should be a duration between 3 months and 2 years
- Are experiencing treatment-resistant depression, defined as failing 2, 3, or 4 pharmacological treatments for their current episode of depression

Other criteria will need to be met to confirm a participant's eligibility for the COMP 006 study.

Why Take Part?

We cannot promise that participants will directly benefit from joining because the effectiveness of COMP360 is what the study is investigating.

If you join the study:

- You will be helping doctors learn more about this therapy, which may help others with TRD in the future
- You will receive close care and monitoring of health and symptoms of depression throughout the study
- Reimbursement may be available for study-related travel expenses

Potential Risks and Discomforts to the Study

Withdrawing from antidepressant medication can be challenging for some people. Sometimes coming off antidepressants can be associated with a worsening of depressive symptoms.

The investigational study drug COMP360 is at a research stage so it may have side effects that are not known at this time. As with any new medication there is a risk that unexpected adverse effects may occur. The study team will be able to discuss this with you in more detail.

COMP 006