Study Purpose

The purpose of the [redacted] Study is to evaluate the safety and efficacy of a once-daily oral investigational medication on improving symptoms of major depressive disorder (MDD) in patients who are having an inadequate response to antidepressant medication(s).

Refer a Patient

If you have a patient who may be eligible for this research study, please contact the research site listed here for more information. The site staff will be able to answer any questions about the research study. Each potential participant will be required to have a visit with the study doctor to evaluate if they qualify. Those who do qualify and enroll will receive the investigational medication and study-related care at no cost to them or their families. Any patients you refer to this research study will be seen for study-related reasons only.

The research site closest to you is:

[SITE CUSTOMIZATION BLOCK]

[redacted]

FOR HEALTHCARE PROFESSIONALS

About the [redacted] Study

[redacted]

Design

The [redacted] Study is a phase 2, double-blind, placebo-controlled research study to evaluate the safety and efficacy of [redacted] on improving symptoms of MDD. Participants will be randomized 1:1:2 to receive either the investigational medication (at 2 different doses) or placebo and will be able to stay on their current antidepressant medication(s) while in the research study.

About the Investigational Medication

[redacted] is a tablet that is taken by mouth once a day in the morning. Participants will be randomized to receive either: 1 mg [redacted], 3 mg [redacted], or placebo. Participants will receive their first dose of the assigned study treatment at the study site on Day 1 (Week 1). The investigational medication or placebo will be taken at home each day except during Day 28 and Day 56. The investigational medication or placebo should be taken with 8 oz. (240 mL) of water and may be taken with or without food.

Study Participation

The total duration of the [redacted] Study for each participant is approximately 14 weeks. This includes a 4-week screening period, 8-week treatment period, and 2-week follow-up period. There will be 6 on-site visits and 2 phone calls with the study team throughout the research study.

Key Eligibility Criteria

Eligible participants must:

- Be 18 to 65 years of age (inclusive)
- Have a confirmed diagnosis of MDD
- Have had inadequate response to up to 5 oral antidepressant medications
- Be currently on stable pharmacological treatment for depression
- Not be pregnant or breastfeeding
- Not have a current psychiatric disorder other than MDD
- Not have a significant risk of suicidal or violent behavior
  - Participants must not have suicidal ideation of type 4 (active suicidal ideation with some intent to act, without specific plan) or type 5 (active suicidal ideation with specific plan and intent) based on the C-SSRS in the past 12 months before screening

Additional eligibility criteria may apply.