

Summary: A Phase 11a Multicenter, Randomized, Double-Blind, Double Dummy, and Placebo-and Active-Controlled Study to Investigate the Safety and Efficacy of an Investigational Medication Administered to Individuals with Major Depressive Disorder

Inclusion Criteria:

- Subjects able to read and understand the consent forms, complete study related procedures, and communicate with the study staff
- Subjects must be aged 18-60 years inclusive at screening (visit 1)
- Subjects within a BMI of ≥ 18 to ≤ 30 .
- Subjects must have a confirmation of a diagnosis of MDD, moderate or severe.
- Subjects must be in good general health prior to study participation with no clinically relevant abnormalities as assess by the investigator and determined by; medical history, physical examination, and laboratory evaluations.
- Subjects must have a negative urine test for drugs of abuse at screening and baseline.
- Female subjects of childbearing potential must have a negative serum pregnancy test at screening and baseline.
- Subjects must agree to use a medically acceptable method of contraception throughout the entire study period.

Exclusion Criteria:

- Subjects with a history or current diagnosis of any of the following disorders:
 - Bipolar Disorder, Schizophrenia or any other Psychotic Disorder, Obsessive Compulsive Disorder, Mental Retardation, Pervasive Developmental Disorder, or Cognitive Disorder, Substance Abuse within 6 months or study entry or Substance dependence within 12 months of study entry, Anorexia Nervosa or Bulimia Nervosa, Post Traumatic Stress Disorder, Borderline or Antisocial Personality Disorder
- Subjects with a diagnosis of Active Generalized Anxiety Disorder (GAD) or panic disorder that precedes the current episode of MDD
- Subjects with a current or past history of inadequate response to more than one class of antidepressant medications or inadequate response to more than two SSRIs
- Subjects who have not been previously treated with at least one antidepressant medication with an adequate dose and duration.
- Subjects who are deemed to be at significant risk for suicidal or violent behavior.
- Subjects who are assessed as needing to initiate a course of cognitive behavioral therapy during the study or who have initiated or terminated cognitive behavioral therapy, within 3 months of the study.
- Subjects who have been treated with an injectable depot neuroleptic within 60 days prior to baseline (visit 2).
- Subjects who have received treatment with clozapine within 6 months prior to baseline.
- Subjects who have received ECT treatment within 6 months prior to screening (visit 1), or who plan to receive ECT treatment during the study.
- Subjects who have taken MAOIs within 3 weeks prior to Baseline (visit 2)
- Female subjects who are pregnant or breastfeeding.

**this list is not all inclusive.

Contact:

Kelly Knoebber-Carr; Certified Clinical Research Coordinator

Telephone: 785-270-4636

Email: kknoebbe@stormontvail.org