Major Depressive Disorder (MDD)

About 16.2 million adults in the United States will have at least one episode of MDD in their lives,[1] with about twice as many women diagnosed as men.[2] It's the number one cause of disability in the U.S.,[3] and more people are being diagnosed with mental disorders every year.[4]

Common symptoms of MDD are:

- Depressed mood nearly every day
- Markedly diminished interest or pleasure from most activities
- Weight loss or gain (5%)
- Insomnia or hypersomnia
- Psychomotor agitation
- Fatigue or loss of energy
- Feelings of worthlessness or guilt
- Diminished concentration
- Suicidal ideation

If left untreated, MDD can significantly impair a person's ability to perform daily life activities. The current standard of care is pharmacological treatments, talk therapy, and/or other interventions. Patients who have not achieved adequate symptom relief may want to consider participating in the Shoreline Study.

SHORELINE
STUDY

For more information about the Shoreline Study, or to refer a patient, please contact:

ShorelineMDDstudy@sagerx.com

ShorelineMDDStudy.com

University of Michigan
4250 Plymouth Road
Ann Arbor, MI 48105
(734) 232-0389

[1] https://www.nimh.nih.gov/health/topics/depression/index.shtml. Accessed September 18, 2018

[2] https://www.nimh.nih.gov/health/statistics/major-depression.shtml. Accessed September 18, 2018

[3] http://www.apa.org/helpcenter/data-behavioral-health.aspx. Accessed September 18, 2018

[4] https://www.bcbs.com/the-health-of-america/reports/major-depression-the-impact-overall-health. Accessed September 18, 2018

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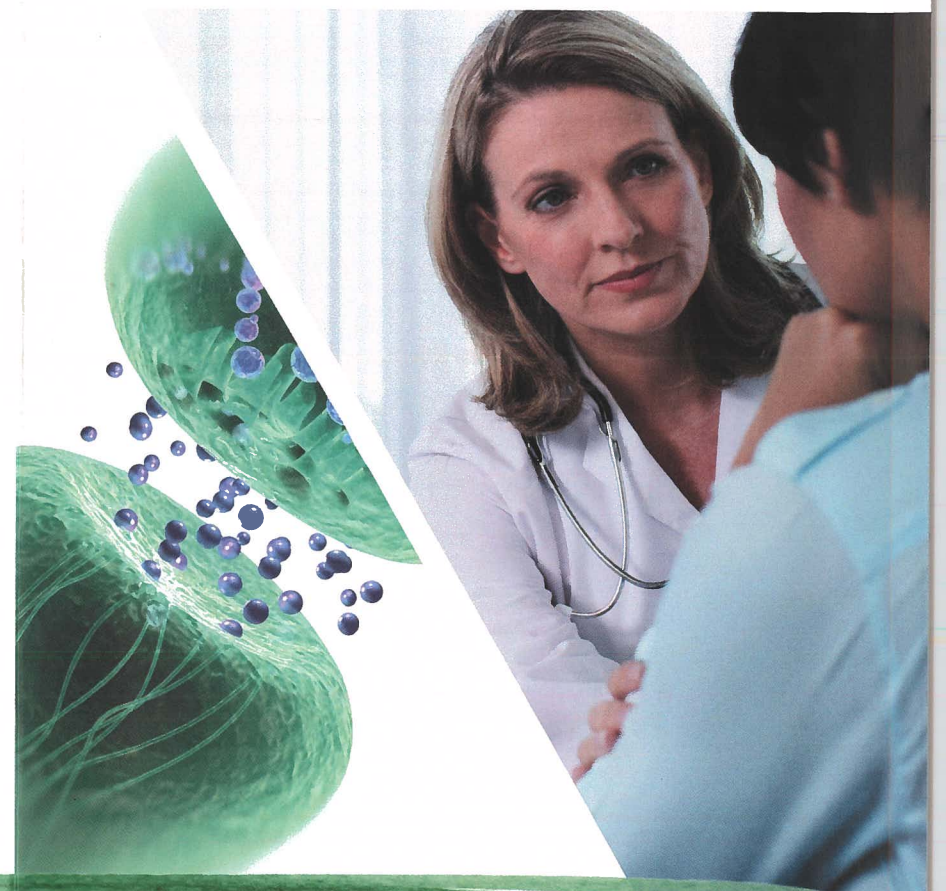
NOW ENROLLING

SHORELINE
STUDY

A clinical research study evaluating an **investigational medication** in **MAJOR DEPRESSIVE DISORDER**



Learn more:

Visit ShorelineMDDStudy.com

Shoreline Study

The Shoreline Study is a Phase 3, open-label, 1-year study of the safety and need for re-treatment with SAGE-217 in adults with major depressive disorder (MDD), as assessed by the Hamilton Depression Rating Scale (HAM-D).

Key Inclusion Criteria

- Men or women 18-75 years
- Current episode of MDD, with symptoms present for at least a 4-week period*
- MADRS total score of ≥ 28

**As diagnosed by Structured Clinical Interview for Diagnostic and DSM-V Clinical Trial Version (SCID-5-CT).*

Key Exclusion Criteria

- Active psychosis
- Attempted suicide associated with the current episode of MDD
- Medical history of seizures
- Psychiatric history of bipolar disorder, schizophrenia, and/or schizoaffective disorder
- Medical history of mild, moderate, or severe substance use disorder (including benzodiazepines) diagnosed using DSM-5 criteria in the 12 months prior to screening
- History of sleep apnea
- Treatment-resistant depression: defined as persistent depressive symptoms despite treatment with adequate doses of antidepressants within the current episode (excluding antipsychotics) from 2 different classes for at least 4 weeks of treatment.

NOTE: Other protocol-defined inclusion/exclusion criteria may apply.

Patient Involvement in the Shoreline Study

Study Duration: approximately 56 weeks

Study Period	Purpose	Duration	Number of Visits
Screening	Determines eligibility	Up to 28 days	1
Initial Treatment Period	Administer 14-day treatment with SAGE-217	14 days	3
Follow-up	Evaluate overall health and MDD symptoms	14 days	1
Observational Period	Assess MDD symptoms and the need for additional cycle(s) of treatment with SAGE-217	48 weeks	At least 6 (approx. every 8 weeks)

All study-related medication and medical care will be provided at no cost. Transportation may be available for those who require assistance.

Patients currently taking a stable antidepressant dosage may be able to stay on their medication during the study.

SHORELINE
STUDY

About SAGE-217

SAGE-217 is an oral compound that has been shown in vitro to be a positive allosteric modulator of synaptic and extrasynaptic $GABA_A$ receptors. The GABAergic system is the major inhibitory-signaling pathway of the brain, and contributes to regulating CNS function.

The investigational medication is thought to target the brain in a new way. It is being studied as a 2-week treatment, with the option for additional 2-week treatment periods as needed during an observational period.

For more information about this trial, please visit:
ClinicalTrials.gov/ct2/show/NCT03864614