

A Randomized, Double-Blind, Parallel-Group, Dose-Controlled Study

Evaluating the Safety and Efficacy of RE104 for Injection in the Treatment of Adjustment Disorder in Patients with Cancer and Other Medical Illnesses



This study is sponsored by Reunion Neuroscience, Inc.

If you are caring for patients with serious medical conditions such as cancer, Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS), Parkinson's disease (PD), or idiopathic pulmonary fibrosis (IPF) who are showing signs of emotional distress due to their medical illness, please consider our clinical study of an investigational treatment for adjustment disorder.

Study Objectives

The investigational product, RE104, is a prodrug of 4-HO-DiPT, a unique psychedelic compound structurally related to the active metabolite of psilocybin, psilocin. RE104 is being evaluated for its potential to reduce emotional symptoms, such as sadness, anxiety, and hopelessness, in patients with adjustment disorder (AjD) related to serious medical illnesses.

RE104 for Subcutaneous Injection (RE104) is being explored in the treatment of AjD as a novel serotonergic antidepressant therapeutic candidate because of the potential for rapid symptom relief, as well as sustained response after a single, short psychedelic period of 3 - 6 hours. RE104 has been evaluated in several animal models, a first-in-human phase 1 clinical trial (FT-104-101), and a phase 2 clinical trial (RE104-201-PPD) in Postpartum depression.

Primary Objective:

- To evaluate the effect of 30 mg RE104 on depressive symptoms in participants with adjustment disorder (AjD) compared to 1.5 mg RE104

Secondary Objectives:

- To evaluate the effect of 30 mg RE104 on anxiety symptoms in participants with AjD compared to 1.5 mg RE104
- To evaluate the safety of RE104

Study Design

This is a randomized, double-blind, multicenter, Phase 2 clinical trial. Participants will be randomly assigned in a 1:1 ratio to receive either 30 mg or 1.5 mg of RE104.

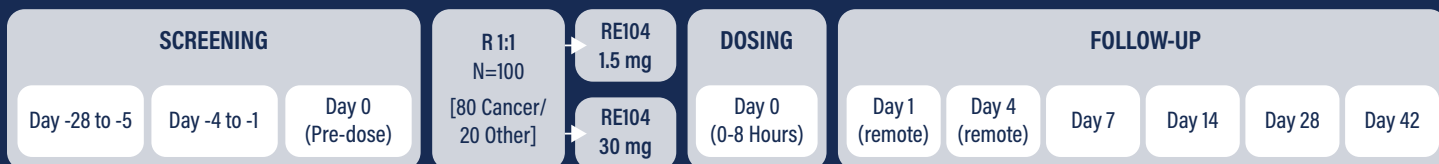
Participants will undergo a screening period of up to 28 days prior to dosing. Pre-dose assessments will be completed on Day -4 to -1 and Day 0 to ensure continued eligibility and suitability of participants for dosing.

RE104 will be administered as a subcutaneous injection at the Study Center. While the post-dose acute experience phase of the dosing session is expected to last approximately 3 hours, post-dose session monitoring will continue for 8 hours post-dose under the supervision of two qualified Session Monitors. Participants will remain in the Study Center under general observation for post-dose assessments, routine safety monitoring, and discharge readiness evaluation.

Following the dosing session, participants will be followed for approximately 6 weeks through several in-person and remote follow-up visits.



Study Schema



Key Inclusion Criteria

- Adults aged 18 to 80 years
- Diagnosis of adjustment disorder with depressed mood or mixed anxiety and depressed mood (DSM-5-TR criteria)
- Onset of symptoms related to:
 - Cancer (stages 1-4)
 - ALS
 - MS (relapsing-remitting)
 - Parkinson's disease
 - Idiopathic pulmonary fibrosis (IPF)
- Minimum of 4-week symptom duration
- Projected life expectancy of ≥ 6 months
- Ambulatory and capable of self-care
- Willing to delay starting new depression or anxiety treatments during the study period
- Has an adult (e.g., family member, caregiver, or trusted friend) available to escort them home from the dosing session.

Key Exclusion Criteria

- History of central nervous system (CNS) malignancy or active disease
- Significant suicide risk or suicide attempt in prior 12 months
- History of bipolar disorder, schizophrenia, schizoaffective disorder, hallucinations, and/or psychotic disorder
- History of borderline personality disorder or a first-degree family history of psychosis or bipolar disorder
- Medically significant condition, including but not limited to:
 - Neurologic disorders (other than those intended for the study)
 - Uncontrolled diabetes
 - Epilepsy or history of seizures (other than childhood febrile seizures)
 - Severe cardiovascular disease
 - Hepatic failure
 - Renal failure (e.g., creatinine clearance < 30 mL/min)
- Currently pregnant or breastfeeding individuals
- Participation in another clinical trial within 30 days of screening

Additional eligibility criteria will be assessed at the time of screening. Please present potential patient cases to the medical monitor if uncertain about any eligibility criteria.

For more information about The REKINDLE Study, please contact the study staff member(s) listed below with potential patients or questions:



Tucson Site Principal Investigator:
Francisco A. Moreno, MD
fmoreno@arizona.edu
(520) 626-5327