



THIEVON-WRIGHT

CONSULTING GROUP®

Thievon-Wright Consulting Group
12 New Providence Road, Watchung, NJ 07069
www.cnssites.com
Office: (908) 756-4411 • Fax: (908) 756-1122
Email: info@cnssites.com

Depression Case Study 2

A Phase IIa, Multi-Center, Randomized, Double-blind, Placebo- controlled, Parallel-Group Study to Assess the Antidepressant Effect and Onset of Effect of XXXXX in Treatment-Resistant Major Depressive Disorder Patients

Robert Litman, MD

Key Elements:

- Inpatient
- Complex Infusion Study

Phase: 2a

Indication: Major Depressive Disorder

of Subjects: 13 Randomized; 13 completed; 26% of study total

In-patient Period: 5 days

Objectives

Primary

Change from baseline to 24 hours in the Montgomery-Åsberg Depression Rating Scale

Secondary

Safety and tolerability

PK/PD relationship of IV doses with MADRS and cognitive function

Comparison of treatment group vs. placebo

- Montgomery Åsberg Depression Rating Scale (MADRS),
- Visual Analogue Scale (VAS),
- Clinician-Administered Dissociative States Scale (CADSS)
- Brief Psychiatric Rating Scale (BPRS),
- Beck Depression Inventory (BDI)
- Clinical Global Impression (CGI)
- CogState Cognition Battery

Pharmacodynamic Assessments

Montgomery-Åsberg Depression Rating Scale (MADRS)

Day -1, D1, D2, D3, D4, f/u. Day 2, 3, & 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

Visual Analogue Scale (VAS)

Day -1, D1, D2, D3, D4, f/u. Day 2, 3, & 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

Clinician-Administered Dissociative Status Scale (CADSS)

Day -1, D1, D2, D3, D4, f/u. Day 2, 3, & 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

Brief Psychiatric Rating Scale (BPRS)

Day -1, D1, D2, D3, D4, f/u. Day 2, 3, & 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

Beck Depression Inventory (BDI)

Day -1, D1, D2, D3, D4, f/u. Day 2, 3, & 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

Clinical Global Impression (CGI)

Day -1, D1, D2, D3, D4, f/u. Day 2, 3, & 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

CogState Computerized Cognition Battery

D-1, D1, D2, D3, D4, f/u. On Day 2, 3, and 4: 1.5hrs pre-dose, 1hr, 4hr, 24hr post dose

Pharmacokinetic Assessments

Day 1: 0.25 pre-dose, 1, 3, 8, and 24 hr post-dose

Day 2: 0.25 pre-dose, 1, 3, 8, and 24 hr post-dose

Safety

Electrocardiograms (ECG)

12 lead ECG screen, f/u

Digital ECGs D1: 0.25 hr pre-dose, 0.25 hr, 0.5 hr, 0.75hr, 1hr, 2hr, 3hr, 3.5hr, 4hr, 8hr, 24hr post dose

Clinical laboratories: Screen, D-1, D2, D7

Vital Signs: Orthostatic and semi-reclining blood pressure on D-1, D1, D2, D3, D4, D7 f/u