



**THIEVON-WRIGHT**

CONSULTING GROUP®

**Thievon-Wright Consulting Group**

12 New Providence Road, Watchung, NJ 07069

[www.cnssites.com](http://www.cnssites.com)

Office: (908) 756-4411 • Fax: (908) 756-1122

Email: [info@cnssites.com](mailto:info@cnssites.com)

# Depression Case Study 3

**A Phase 1, Single-center, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, and Pharmacokinetics of Ascending Multiple Oral Doses of XXXXX as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder**

**Rick Mofsen, DO**

### Key Elements:

- 16 Patient Cohorts
- Complex Procedure Schedule

**Indication:** Major Depressive Disorder

**# of Subjects:** 32 Randomized (2 cohorts of 16)

**In-patient Period:** 18 days

### Objectives

#### Primary

To determine the safety and tolerability of XXXXX when administered as adjunctive therapy to other antidepressant therapy (ADT) to MDD patients following multiple ascending oral doses

#### Secondary

To determine the steady-state pharmacokinetics (PK) of XXXXX and its metabolites in MDD patients following multiple oral doses of XXXXX

### Ratings

Mini International Neuropsychiatric Interview (M.I.N.I.), Simpson Angus Scale (SAS), Abnormal Involuntary Movement Scale (AIMS), Barnes Akathisia Rating Scale (BARS), Columbia-Suicide Severity Rating Scale (C-SSRS)

### Lab Assessments—24 per subject

Screening

Day -1

Days 1: pre-dose

Days 16: pre-dose Days 17: pre-dose

Day 18: pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12, 16, 24, 48, 72, 96, 120, 144, 168, 192, and 216 hours post-dose

### ECGs—42 per subject

Screening

Day -1

Day 1: pre-dose, 2, 4, and 6 hours post-dose

Days 2 to 4: pre-dose

Days 5: pre-dose, 2, 4, 6, 8 and 12 hours post-dose

Days 6 to 17: pre-dose only

Days 18: pre-dose, 2, 4, 6, 8, 12, 24, 48, 72, 96, 120, 144, 168, 192, and 216 hours post-dose

- *Resting 12-lead ECG performed after the subject has been supine at rest for 10 minutes*

### Vitals—42 per subject in triplicate = 126

Screening

Day -1

Day 1: pre-dose, 2, 4, and 6 hours post-dose

Days 2 to 4: pre-dose

Day 5: pre-dose, 2, 4, 6, 8 and 12 hours post-dose

Days 6 to 17 at pre-dose

Day 18: pre-dose, 2, 4, 6, 8, 12, 24, 48, 72, 96, 120, 144, 168, 192, and 216 hours post-dose

- *Blood pressure and heart rate taken in the supine, sitting, and standing positions after remaining for 3 minutes in each position.*
- *Respiratory rate and oral body temperature taken with the subject in the supine position.*