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Schizophrenia Bipolar Phase 1 Case Study

An Open-Label, Randomized, Two Treatment, Multi-Site, Multiple Dose, Steady State, Three-Way, Reference-Replicated Crossover, Pharmacokinetic Study To Determine The In-Vivo Bioequivalence Between XXXXX XXmg Sublingual Tablet And XXXX XXmg Sublingual Tablet

Woodland International Research Group

Phase: 1
Indication: Schizophrenia (Stable) or Bipolar (stable) subjects
Rapid Study Start-up: Contracting, regulatory, and site initiation completed within 48 hours
# of Subjects: 11 (study average was 5-6 completed subjects per site)
In-patient Period: 6 full bed days with an additional 11.5 days of non-treatment, confinement days per subject
Completion Rate: ~91% compared to a study average of 75%
Other Study Information: Woodland completed ~26% of study enrollment out of 8 total sites.

Key Elements:

- Rescue Study
- Ultra Rapid Start with high retention

OBJECTIVES

Primary

Establish the pharmacokinetic bioequivalence between XXXXX sublingual tablets and XXXXX sublingual tablets.
ECGs—5 per subject

Secondary

Compare the safety profiles of the test and reference products by examining the adverse events profiles of the two products.

PK Lab Draws—9 per subject
Day 5, Day 6, Day 12, Day 13, Day 19 and Day 20. PK draws performed on days 7, 14 and 21 at hour 0 (pre-dose), 0.25, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0. All pre-dose draws were performed within 5 minutes prior to dosing.

Vitals—14 per subject
Daily

- Assessed within 15 minutes before and within 30 minutes after the morning dose

ECGs—5 per subject
Day -7
Day 1
Day 8
Day 15
Day 24

- Standard 12-lead ECGs

Hematology / Chemistry—6 per subject
Day -7
Day 1
Day 7
Day14
Day 21
Day 24