Relationship of Sleep Quality and Fibromyalgia Outcomes in a Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study of Bedtime, Rapidly Absorbed, Sublingual Cyclobenzaprine (TNX-102 SL)

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Baseline Characteristics Patient Disposition

Background

Caucasian (%) 88 (87%) 91 (88%)

Count, mean (SD) 14.2 (2.90) 14.7 (2.56)

Safety Evaluation

• Daily Sleep Diary (0-10 NRS average for fibromyalgia, meeting all of the following criteria:

  - Fibromyalgia Impact Questionnaire-Revised (FIQ-R) (0-10) Numerical Rating Scale score ≥9
  - Restorative sleep is believed to play an important role in the pathophysiology of fibromyalgia

• TNX-102 SL Adverse Events

  - Respiratory, thoracic and mediastinal disorders Cough
  - General disorders and administration site conditions Product taste abnormal

Methods

BESCIT Study Characteristics and Endpoint Measures: BESCIT – Bedtime Sublingual TNX-102 SL in Fibromyalgia/Intervention Therapy

• Study conducted in the U.S. and Canada, and patients enrolled and randomly assigned (double-blind) to TNX-102 SL (n=103) or Placebo (n=102) for 12 weeks

• 272 patients were included in the primary efficacy analysis

Prior Sleep Quality Affects Pain

• Patient data on file, Tonix Pharmaceuticals.

TNX-102 SL Adverse Events

• Local administration site oral hypoesthesia (transient tongue or sublingual numbness) was reported in 45 out of 103 treated patients

• Only 3 patients withdrew from participation in the study due to local adverse events

Conclusions

• Improvements in measures of sleep quality with bedtime administration of TNX-102 SL correlate with reductions in fibromyalgia pain symptoms

• Local site administration narcotic of oral hypoesthesia and abnormal product taste were the only commonly reported adverse events with an incidence of <5% and at least twice the rate of placebo

• Sleep quality improvements during preceding nights positively influence subsequent fibromyalgia pain. Increasing duration (up to 5 prior days) of sleep quality improvement is increasingly predictive of the current day’s pain

• TNX-102 SL correlate with reductions in fibromyalgia pain symptoms

• Improvements in sleep quality than with placebo. (Lead-lag statistical analyses: P<.001)

References

1. Data on file, Tonix Pharmaceuticals.
2. TNX-102 SL is a investigational New Drug and has not been approved for any indication.