**TNX-102 SL** is a sublingual cyclobenzaprine (CBP) formulation designed for rapid absorption and long-term bedtime use. This novel formulation was developed to leverage CBP’s established analgesic effects in fibromyalgia while minimizing the risk of sedation associated with CBP formulations taken during the day. TNX-102 SL is a unique eutectic formulation of cyclobenzaprine hydrochloride (CBP-HCl) and sodium dihydrogen phosphate (KH2PO4) that protects CBP-HCl from base and makes stable tablets with rapid absorption properties. TNX-102 SL was evaluated in the BESTFIT study, a 12-week, randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by ACR criteria. The study was designed to evaluate the safety and efficacy of TNX-102 SL in fibromyalgia.

### Methods

**BESTFIT Study Characteristics and Endpoint Measures**

**TNX-102 SL** was evaluated in the BESTFIT study, a 12-week, randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by 2010 ACR criteria. The study enrolled 205 patients, with 103 receiving TNX-102 SL and 102 receiving placebo. The study was conducted at 17 centers in the United States.

### Key Secondary Efficacy Endpoints

- **Proprietary Cyclophilin Inhibitor:** TNX-102 SL has a unique eutectic formulation that protects cyclobenzaprine (CBP) from base and makes stable tablets with rapid absorption properties.

### Baseline Characteristics

- **BMI (SD):** 30.0 (5.5) vs. 30.0 (5.7)

### Adverse Events

- **Adverse Events Reported in More than 2 Subjects in Either Group**:
  - **Infections and infestations**: Upper respiratory tract infection (4.0%), sinusitis (3.0%)
  - **Gastrointestinal disorders**: Nausea (14.7%), dyspepsia (14.7%), diarrhea (5.0%)

### Conclusions

- **TNX-102 SL** provides analgesia with a rapid onset of action.
- **TNX-102 SL** significantly improved global and functional measures such as PGIC and FIQ-R total score (p < .001).
- **TNX-102 SL** was associated with a lower incidence of adverse events, with the most common being local site oral hypoaesthesia.
- **TNX-102 SL** improved sleep quality, mobility, and global perception of change.
- **TNX-102 SL** improved pain endpoints, including peak pain intensity and average daily pain score.

### References

- *1* Tonix Pharmaceuticals, Inc., *Gendreau Consulting LLC, University of Michigan, University of Cincinnati, Tonix Pharmaceuticals*
- *2* Michael Gendreau, 3*Daniel J. Clauw, 4*Lesley M. Arnold, 5*Judy Gendreau, Bruce Daugherty, Amy Forst*
- *3* Seth Lederman, *R Michael Gendreau, 2Daniel J. Clauw, 4Lesley M. Arnold, 5Judy Gendreau, Bruce Daugherty, Amy Forst*