TONIX PHARMACEUTICALS

Results of Phase 3 RELIEF Study in Fibromyalgia

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TNX-102 SL: Potential Treatment for Fibromyalgia

Volkswagen Check Engine [Photograph]. (2011, October 14). Wikipedia

- Fibromyalgia is considered a central nervous system disorder with symptoms that include: chronic widespread pain, nonrestorative sleep, fatigue, diminished cognition and mood disturbances
- Believed to result from inappropriate pain signaling in central nervous system in the absence of peripheral injury[1]
- An estimated 6-12 million adults in the U.S. have fibromyalgia[2], 90% of whom are women
- Causes significant impairment in all areas of life[3]
  - Lower levels of health-related quality of life – reduced daily functioning
  - Interference with work (loss of productivity, disability)
- Fewer than half of those treated for fibromyalgia receive complete relief from the three FDA-approved drugs[4]
- Substantial off-label use of narcotic painkillers and prescription sleep aids[5]
  - Among those diagnosed, more than one-third have used prescription opioids as a means of treatment[6]

[1] Phillips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.
[2] American Chronic Pain Association (www.theacpa.org, 2019)
[3] Schaefer et al., Pain Pract, 2015.
[4] The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica); Duloxetine (Cymbalta); Milnacipran (Savella)
[5] Patient Trends: Fibromyalgia", Decision Resources, 2011.
[6] Berger A, Dukes E, Martin S, Edelsberg J, Oster G, Int J Clin Pract, 2007; 61(9):1498–1508.

Overview of TNX-102 SL*

Protectic® proprietary formulation of cyclobenzaprine that supports sublingual administration

TNX-102 SL is a non-opioid, centrally-acting analgesic that works by improving sleep quality

◇ Scientific Rationale for Protectic® Formulation ◇

- Engenders unique pharmacokinetic and pharmacodynamic properties that emphasize sleep properties of cyclobenzaprine while minimizing undesirable properties
- Potential therapeutic value in a constellation of disorders where sleep disturbances are:
  - Co-morbid
  - Involved in the onset, progression and severity of the disease

*TNX-102 SL is in clinical stage of development and not approved for any indication

TNX-102 SL: Differentiation from Oral Formulations

FEATURE	BENEFIT	ADVANTAGE
Cyclobenzaprine	40+ years as oral medication	Established safety record
Formulation: Protectic®	Allows submucosal absorption	Not achievable with oral formulation
Administration: sublingual	Bypasses gut	Avoids first-pass metabolism; reduced formation of "activating" metabolite
Pharmacokinetic profile	Rapid absorption (peak at ~4 hours, low trough levels 8-24 hours)	Desired profile for nighttime action
Dose: low (2.8 to 5.6 mg)	Recruitment of high affinity receptors (5-HT_{2A}, α_1, H_1, M_1)	Complimentary multi-modal mechanism of action with less risk of off-target interference

Study Design: Phase 3 RELIEF

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia in 39 U.S. sites (full sample size N=503)
- Adaptive Design: one unblinded interim analysis based on 50% of randomized participants

TNX-102 SL once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets)[1] *N= 248*

Placebo once-daily at bedtime
N= 255

14 weeks

[1]Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

Primary endpoint (Week 14):

- Daily diary pain severity score change (TNX-102 SL 5.6 mg vs. placebo) from baseline in the weekly average as measured by the numerical rating scale (NRS), using mixed model repeated measures analysis with multiple imputation (MMRM with MI)

Key Secondary endpoints (Week 14):

- Patient Global Impression of Change responder analysis
- Fibromyalgia Impact Questionnaire - Revised (FIQ-R) Symptom Domain score
- FIQ-R Function Domain score
- PROMIS Sleep Disturbance instrument T-score
- PROMIS Fatigue instrument T-score
- Weekly average of the daily diary assessment of sleep quality

Pivotal efficacy study to support NDA approval

RELIEF Study: Primary Efficacy Endpoint[1]

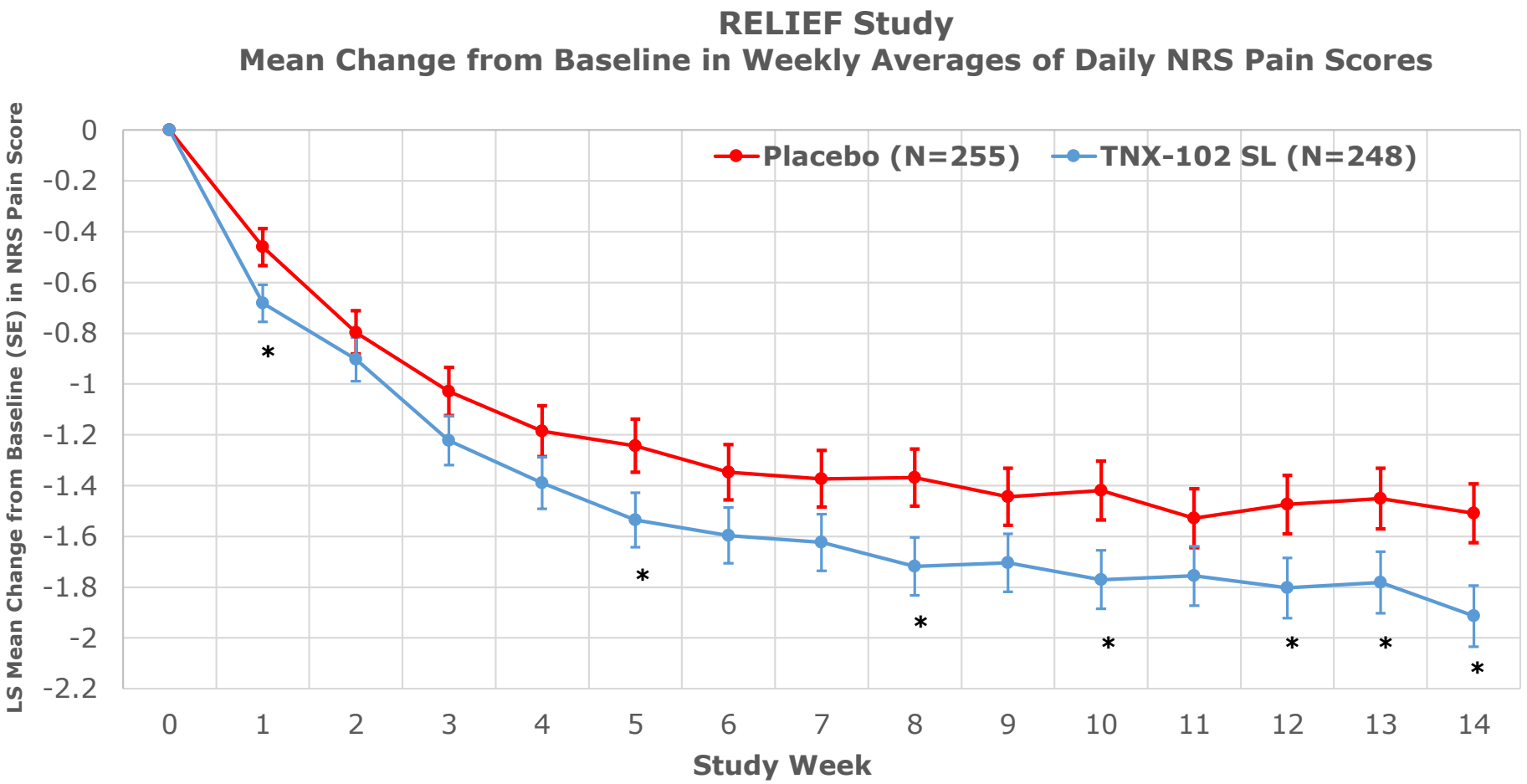
Primary Outcome Measure at Week 14	Placebo (N=255)	TNX-102 SL[2] (N=248)	Treatment Difference	P value
	LS Mean Change from Baseline (SE)	LS Mean Change from Baseline (SE)	Difference in LS Mean Change from Baseline Between TNX-102 SL and Placebo (SE)	
Daily Pain Diary, NRS	-1.5 (0.12)	-1.9 (0.12)	-0.4 (0.16)	0.010*

Statistical Method: Mixed Model Repeated Measures analysis with Multiple Imputation
*p<0.0452 (requisite p-value hurdle for full study after Interim Analysis)
[1] Same primary endpoint analysis for FDA approvals of Cymbalta® and Lyrica® in fibromyalgia
Abbreviations: LS = least squares; NRS = numeric rating scale; SE = standard error

- The successful primary efficacy analysis is also supported by an exploratory 30% responder analysis of daily diary pain, which indicated 46.8% on TNX-102 SL versus 34.9% on placebo achieved a 30 percent or greater reduction in pain (logistic regression; odds ratio [95% CI]: 1.67 [1.16, 2.40]; p=0.006)
  - 30% responder analysis was the primary analysis in F301 AFFIRM study of TNX-102 SL 2.8 mg
    - Also was the same primary endpoint analysis for FDA approval of Savella® for fibromyalgia

[2] TNX-102 SL is in clinical stage of development and not approved for any indication

RELIEF Study: Primary Efficacy Endpoint (continued)



*p<0.0452

RELIEF Study: Key Secondary Efficacy Endpoints

Outcome Measure at Week 14	Intent-to-Treat Analysis[1]	*P*-value
Non-Specific		
Patient Global Impression of Change	Responder Analysis: Proportion "Much Improved" or "Very Much Improved"	0.058
Fibromyalgia Syndrome-Related		
FIQ-R Symptom Domain	Mean Change from Baseline	0.007[#]
FIQ-R Function Domain	Mean Change from Baseline	0.009[#]
PROMIS Fatigue	Mean Change from Baseline	0.018[#]
Daily Sleep Quality Diary, NRS	Mean Change from Baseline	<0.001[#]
PROMIS Sleep Disturbance	Mean Change from Baseline	<0.001[#]

[#] nominally significant at $p<0.0452$

[1] Combined periods (pre- and post-interim analysis); responder analysis is by Logistic Regression (missing = non-responder); the five mean change analyses are by Mixed Model Repeated Measures with Multiple Imputation

Abbreviations: FIQ-R = Fibromyalgia Impact Questionnaire – Revised; NRS = numeric rating scale; PROMIS = Patient-Reported Outcomes Measurement Information System

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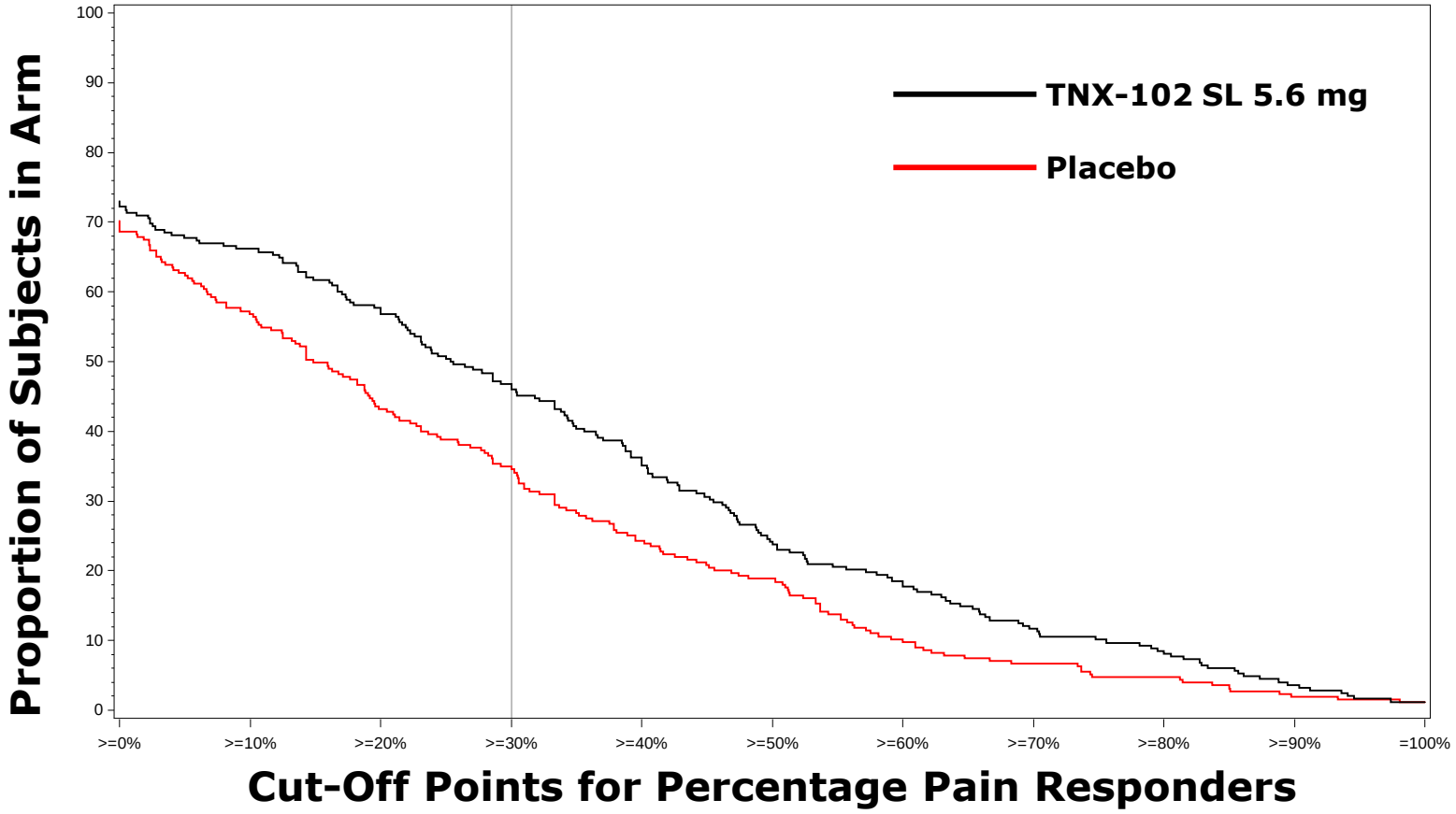
RELIEF Study: Continuous Responder Analysis (CRA) Graph

- The CRA graph allows one to see the proportion of responders over an entire range of cut-off points
- For example, >=30% improvement in pain is considered clinically meaningful in pain studies
- Looking at that vertical line at >=30% and visualizing a horizontal line to the y-axis tells you the proportion of each arm that achieved that level of pain improvement or better (47% for TNX-102 SL and 35% for placebo)
- It can be seen that TNX-102 SL separates from placebo, always at a higher proportion, up to about >=95% improvement



Adverse Events* (AEs) in RELIEF Study

	TNX-102 SL (N=248)		Placebo (N=255)		Total (N=503)	
Administration Site Reactions	**N**	**%**	**N**	**%**	**N**	**%**
Tongue/mouth numbness	43	17.3	2	0.8	45	8.9
Tongue/mouth pain/discomfort	29	11.7	5	2.0	34	6.8
Taste impairment	16	6.5	1	0.4	17	3.4
Tongue/mouth tingling	14	5.6	1	0.4	15	3.0
Systemic Adverse Events	**N**	**%**	**N**	**%**	**N**	**%**
Somnolence/Sedation	14	5.6	3	1.2	17	3.4

* Table reports only AEs at rate of greater than 5% in either treatment arm

No serious and unexpected AEs in RELIEF related to TNX-102 SL

- Systemic AEs comparable with prior studies and consistent with approved oral cyclobenzaprine product labeling
- Oral AEs similar to prior studies with TNX-102 SL, although tongue/mouth numbness at about half the rate in RELIEF

Safety and Tolerability in RELIEF Study

- No new safety signals in RELIEF at TNX-102 SL 5.6 mg dose
- 82.3% in active arm and 83.5% in placebo arm completed the study
- 8.9% in active arm and 3.9% in placebo arm discontinued due to adverse events
- 7 SAEs in study: 2 in active arm and 5 in placebo arm
  - Of 2 in active arm, one was motor vehicle accident with multiple bone fractures, and other was pneumonia due to infection; both deemed unrelated to TNX-102 SL
- Similar oral administration site reactions as in prior studies with TNX-102 SL
- Overall low rates of systemic side effects, highest being somnolence/sedation at 5.6% in active group, 1.2% in placebo

TNX-102 SL Intellectual Property – U.S. Protection expected until 2035

Composition of matter (eutectic):

Protection expected to 2034/2035

- United States Patent and Trademark Office (USPTO) issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020
- European Patent Office (EPO) issued European Patent No. 2968992 in December 2019 (validated in 37 countries). Opposition filed in October 2020 by Hexal AG
- China National Intellectual Property Administration issued Chinese Patent No. ZL 201480024011.1 in April 2019
- Japanese Patent Office (JPO) issued Japanese Patent No. 6310542 in March 2018, Patent No. 6614724 in November 2019, and Patent No. 6717902 in June 2020
- 10 granted patents (Indonesia, Saudi Arabia, New Zealand, Australia, Mexico, Taiwan, Israel, South Africa)
- 31 patent applications pending (4 being allowed in U.S., China, Israel, South Africa)

Composition of matter (sublingual):

Protection expected to 2033

- NZIPO issued New Zealand Patent No. 631144 in March 2017 and Patent No. 726488 in January 2019
- Taiwanese Intellectual Property Office issued Taiwanese Patent No. I590820 in July 2017, Patent No. I642429 in December 2018 and Patent No. I683660 in February 2020
- Australian Patent Office issued Australian Patent No. 2013274003 in October 2018 and Patent No. 2018241128 in September 2020
- JPO issued Japanese Patent No. 6259452 in December 2017
- 20 patent applications pending

Next Steps

- **Results from ongoing 2nd potential pivotal Phase 3 study, RALLY (F306), for TNX-102 SL in fibromyalgia expected in 2nd half of 2021**
  - Same protocol design as RELIEF study
  - Enrollment began in September 2020

- **Following positive results from RALLY, an NDA could potentially be filed in 2022**
  - Long term safety exposure studies completed
  - GMP manufacturing processes mature and 36-month stability established

Conclusion

- **TNX-102 SL is now mid-Phase 3 in fibromyalgia**
  - Millions suffer from this chronic condition
  - Remains an unmet need due to lack of efficacy and intolerable side effects associated with approved drugs, for many patients

- **TNX-102 SL is a differentiated compound with robust IP**
  - TNX-102 SL is a non-opioid, non-addictive, centrally-acting analgesic that could provide a new therapeutic option for fibromyalgia patients
  - Patent protection expected to extend through 2035
    - 5 patents issued in the U.S.

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Q&A