ZELIRA THERAPEUTICS

A Global Biopharmaceutical Company Developing and Marketing Clinically Validated Cannabinoid-Based Medicines

Zelira's Diabetic Nerve Pain Drug Outperforms Big Pharma drug; successful clinical trial against multi-billion-dollar Lyrica®

Demonstrated Safety, Tolerability, and Improved Efficacy in Pain Management

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Highlights

Objective of the study

Comparing Zelira's patent protected, proprietary ZLT-L-007 with Lyrica® with regards to the reduction of diabetic nerve pain

IRB-approved observational multi-arm head-to-head study powered to show statistical significance

Topline Results

ZLT-L-007 materially outperformed Lyrica® in reducing NRS pain scores

Significant decrease in symptom severity observed

ZLT-L-007 met the primary endpoint with no Serious Adverse Events (SAE)

ZLT-L-007 significant decreases in Visual Analog Scale (VAS) and Short form McGill scores- met secondary endpoints

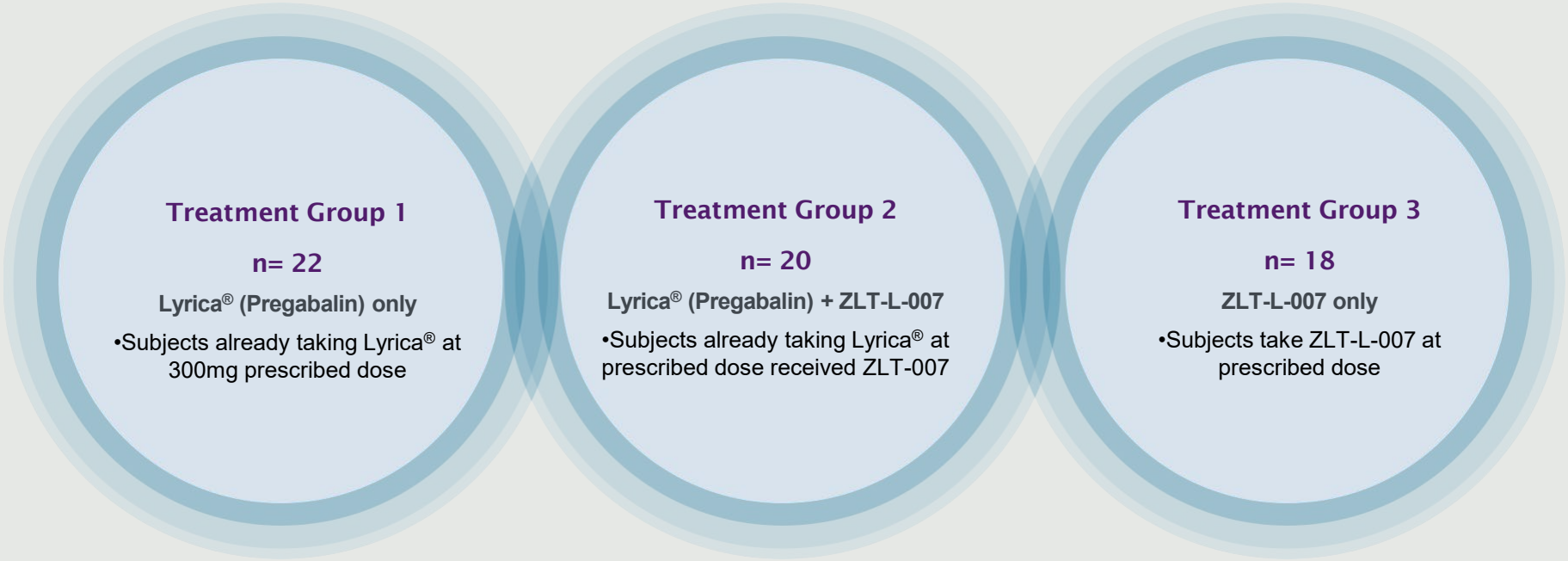
Market Potential

ZLT-L-007 demonstrated improved efficacy, enhanced safety and tolerability profile for diabetic nerve pain, a market in which Lyrica® is an established leader with peak year sales of approximately $5BB*

Next steps - Evaluate further progression of ZLT-L-007 in formal FDA clinical trials as part of Zelira's Launch, Learn & Develop strategy

References:
*-Grand View Research. (2021). Diabetic Neuropathy Market Size, Share & Trends Analysis Report By Disorder (Peripheral, Autonomic, Proximal, Focal), By Treatment (Drug, Radiotherapy, Physiotherapy), By Region, And Segment Forecasts, 2021 - 2028. Retrieved from https://www.grandviewresearch.com/industry-analysis/diabetic-neuropathy-market

Study Design Overview



Dosage and Administration: Group 2 and 3: One capsule of ZLT-L-007 (74.5mg) orally twice daily.

Dosage Adjustment: After two weeks, PI can increase dosing to three times daily. Additional dosing up to four times daily at PI's discretion.

Study Setting: Participants take the study drug in the privacy of their own homes.

Topline Results

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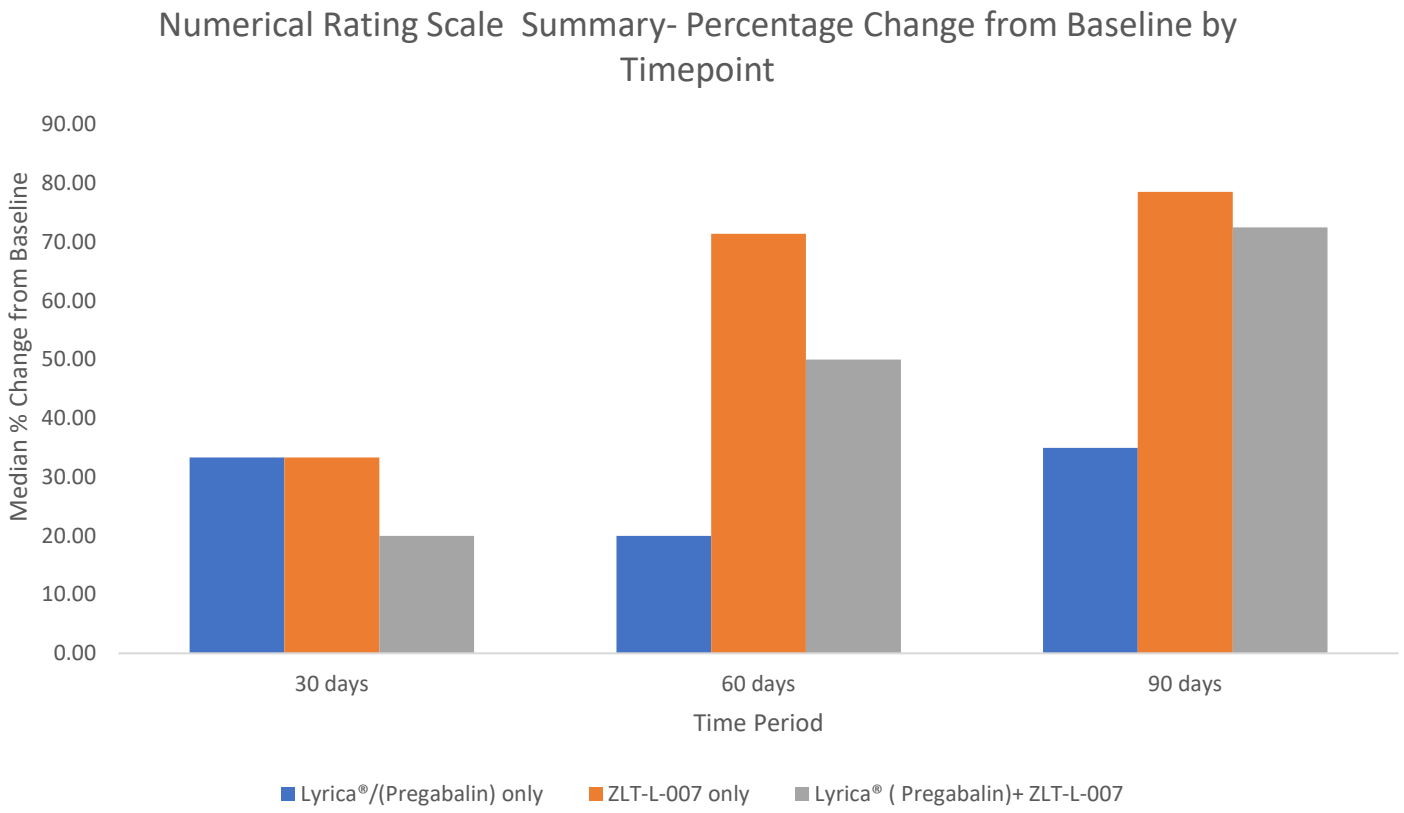
ZLT-L-007 Outperformed Lyrica® -Significant Reduction In NRS Pain Scores, Indicating A Decrease In Symptom Severity



Lyrica® / (Pregabalin) only Group:
30-day follow-up: Median percent change from baseline: -33.33%
60-day follow-up: Median percent change from baseline: -20.00%
90-day follow-up: Median percent change from baseline: -35.00%

ZLT-L-007 only Group:
30-day follow-up: Median percent change from baseline: -33.33%
60-day follow-up: Median percent change from baseline: -71.43%
90-day follow-up: Median percent change from baseline: -78.57%

Lyrica® / Pregabalin + ZLT-L-007 Group
30-day follow-up: Median percent change from baseline: -20.00%
60-day follow-up: Median percent change from baseline: -50.00%
90-day follow-up: Median percent change from baseline: -72.50%

* The median change in baseline for both NRS and VAS results are the same. See chart above.
The observed effect of both NRS and VAS were within the 95% CI.

ZLT-L-007 Was Found To Be Safe And Well-tolerated, Meeting The Primary Endpoint For Safety With No Serious Adverse Events (SAE) And Other Secondary Endpoints

Serious Adverse Events (SAE)	➢ The study met another of its primary endpoint for safety measured by Serious Adverse Event (SAE) report with 0 SAE reports for the duration of the study.
Topline Secondary Endpoints Results	➢ The study met its secondary endpoint for the change in daily pain severity measured by the % change from baseline, Day 30, Day 60, Day 90 for Visual Analog Scale (VAS). . ➢ The study also met several secondary endpoints such as measurable change in the Short Form McGill Pain Questionnaire and NPSI. ➢ There was no significant change in systolic and diastolic blood pressure measures for the participants in the study measured at the different time points

Market opportunity for Zelira's diabetic nerve pain drug

Diabetic neuropathy is a common complication of diabetes, affecting a significant portion of diabetic patients. The rising prevalence of diabetes worldwide is a key factor driving the market growth.

As a commercially available pain medicine, Lyrica® served as a reliable benchmark to gauge the pain relief efficacy offered by our novel candidate, ZLT-L-007.

Lyrica® has historically achieved peak year annual sales of approximately US$5 billion as a patented product, clearly indicating the market potential for Zelira's outperforming pain relief medication.*

Global diabetic neuropathy market size was valued at USD **3.6 billion** in 2020. It is expected to expand at a compound annual growth rate (CAGR) of **5.9%** from 2021 to 2028.*

The positive comparative results and promising potential of Zelira's ZLT-L-007 in the treatment of diabetic nerve pain makes the market opportunity for this drug significant.

References:
*-Grand View Research. (2021). Diabetic Neuropathy Market Size, Share & Trends Analysis Report By Disorder (Peripheral, Autonomic, Proximal, Focal), By Treatment (Drug, Radiotherapy, Physiotherapy), By Region, And Segment Forecasts, 2021 - 2028. Retrieved from https://www.grandviewresearch.com/industry-analysis/diabetic-neuropathy-market

Thank You

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