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Daytime and Nighttime Symptom Improvements Are Associated With Better Quality of Life in Idiopathic Hypersomnia: Findings From LYRICAL

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Objective

- To explore associations between improvements in daytime and nighttime symptoms and quality of life (QoL) among LYRICAL participants with idiopathic hypersomnia taking low-sodium oxybate (LXB)

Conclusions

- Improvements in refreshing nighttime sleep, and separately, daytime sleepiness, were linked to improvements in broader patient-reported outcomes, including cognitive functioning, work productivity, and QoL, over the study period in participants with idiopathic hypersomnia taking LXB
- Limitations include the lack of a comparator group, potential selection and recall bias (participants had been taking LXB for ≥12 weeks at enrollment), and small sample sizes for some analyses
- Survey and qualitative insights from the LYRICAL study highlight the importance of addressing the 24-hour symptom burden of idiopathic hypersomnia with LXB and how restorative sleep and improving daytime sleepiness may translate to measurable real-world gains across a spectrum of function and QoL outcomes

References: 1. Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. **2.** Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale, NJ: Lawrence Erlbaum; 1988. **3.** Bharmal M, et al. *Health and quality of life outcomes*. 2009;7:36. **4.** Chasens ER, et al. *Sleep.* 2009;32(7):915-919. **5.** Reilly MC, et al. *PharmacoEconomics*. 1993;4(5):353-365. **6.** Ma Z, et al. *J Sleep Res.* 2022;31(5):e13552. **7.** Dauvilliers Y, et al. *Neurology.* 2019;92(15):e1754-e1762. **8.** PROMIS Cognitive Function Scoring Manual. 2022. Available at: https://www.healthmeasures.net/images/PROMIS/manuals/Scoring_Manual_Only/PROMIS_Cognitive_Function_Scoring_Manual_03June2022.pdf.

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Disclosures: C Drachenberg, M Whalen, JK Alexander, S Beaty, and **SC Markt** are full-time employees of Jazz Pharmaceuticals who, in the course of this employment, have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. **M Farrell, J D'Souza, E Kim, C Hayes, D Zhang, M Lawrence,** and **CA Graham** are full-time employees of IQVIA, which received funding from Jazz Pharmaceuticals to conduct the study. **LB Herpel** is an Affiliate Assistant Professor at the Medical University of South Carolina; participates in clinical research for Alkermes, Avadel, Axsome Therapeutics, Centessa, Eisai, Eli Lilly, Harmony Biosciences, Idorsia, Jazz Pharmaceuticals, LivaNova/OSPREY, Merck, Noctrix, Roche, Samsung, Sanofi, Suven, Takeda, and Vanda; serves as an advisor to Avadel, Axsome, Eli Lilly, Harmony Biosciences, and Jazz Pharmaceuticals; and serves on the speaker bureau for Avadel and Harmony Biosciences.

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Introduction

- Low-sodium oxybate (LXB; Xywav®) is approved by the US Food and Drug Administration for the treatment of excessive daytime sleepiness or cataplexy in patients 7 years of age or older with narcolepsy and for the treatment of idiopathic hypersomnia in adults[1]
- The LYRICAL (**L**ongitudinal mixed methods stud**Y** of **R**eal-world patterns of use, effectiveness, and treatment satisfaction in adults with **I**diopathic hypersomnia and nar**C**olepsy t**A**king **L**ow-sodium oxybate) study was conducted to better understand the real-world experience of adults with narcolepsy or idiopathic hypersomnia taking LXB treatment
  - This poster reports associations between nighttime and daytime symptoms and quality-of-life (QoL) outcomes for participants with idiopathic hypersomnia; results for the narcolepsy cohort are presented in **Poster 534**
  - Relatedly, **Posters 359** and **360** describe participant-reported effectiveness and treatment satisfaction in narcolepsy and idiopathic hypersomnia, respectively; individualized dosing with LXB for participants with narcolepsy and idiopathic hypersomnia are explored in **Posters 362** and **361**, respectively

Methods

- This longitudinal, mixed-methods study gathered quantitative (survey) and qualitative (interview) data from participants currently taking LXB at enrollment and over the 24-week study period

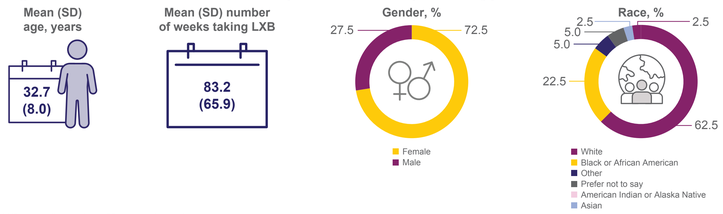
Figure 1. LYRICAL Study Design

[a]Participants were eligible if they were ≥18 years of age at the time the screening form was completed; a US resident; diagnosed with narcolepsy or idiopathic hypersomnia; prescribed and currently taking LXB for narcolepsy or idiopathic hypersomnia; and had been taking LXB for ≥12 weeks prior to completing the screening form. All participants provided written or electronic informed consent.
PRO, patient-reported outcome.

- Online surveys were conducted via an IQVIA-hosted platform between March 2024 and August 2025 and comprised standardized patient-reported outcome (PRO) instruments and *de novo* items; surveys were administered at enrollment, week 12, and week 24
- Virtual 45-minute interviews were conducted using semi-structured discussion guides with a subset of participants at enrollment (n=13) and week 24 (n=12)
  - Interviews were audio-recorded, transcribed, and coded and analyzed using MAXQDA (VERBI Software, 2021) and Microsoft Excel
- Correlation coefficients (r) were used to quantify associations at enrollment between 4 Patient Global Impression of Change (PGI-C) items since starting LXB and PROs assessing symptoms (Idiopathic Hypersomnia Severity Scale [IHSS]; Sleep Inertia Questionnaire [SIQ]), work productivity (Work Productivity and Activity Impairment [WPAI]), cognitive function (PROMIS-Cognitive Function [CF]-Short Form [SF]-8a), sleep-related QoL (10-item Functional Outcomes of Sleep Questionnaire [FOSQ-10]), depression (9-item Patient Health Questionnaire [PHQ-9]), and treatment satisfaction (9-item Treatment Satisfaction Questionnaire for Medication [TSQM-9])
- Correlations were calculated between categorical improvements in Patient Global Impression of Severity (PGI-S) items from enrollment to weeks 12 and 24 and changes in PRO scores over the same time period
- Measurable improvements in PRO scores at weeks 12 and 24 (defined as >0.5 SD improvement from enrollment score) were assessed alongside PGI-S category improvements at weeks 12 and 24
- Polyserial (continuous data) and polychoric (ordinal items) correlations were calculated; thresholds for correlation strength were based on Cohen's cutoffs[2]
  - Minimal: |r| < 0.2
  - Weak: 0.2 ≤ |r| < 0.3
  - Moderate: 0.3 ≤ |r| < 0.4
  - Strong: 0.4 ≤ |r| ≤ 0.6
  - Very strong: |r| > 0.6

Results

Figure 2. Characteristics of Participants With Idiopathic Hypersomnia



LXB, low sodium oxybate; SD, standard deviation.

- Among 40 participants with idiopathic hypersomnia who completed the enrollment survey, the mean age (SD) was 32.7 (8.0) years
- The majority of participants were female (72.5%) and White (62.5%)
- Mean (SD) duration of LXB treatment at enrollment was 83.2 (65.9) weeks or approximately 19 months
- Additional participant characteristics are reported in the Supplement, accessed via the QR code

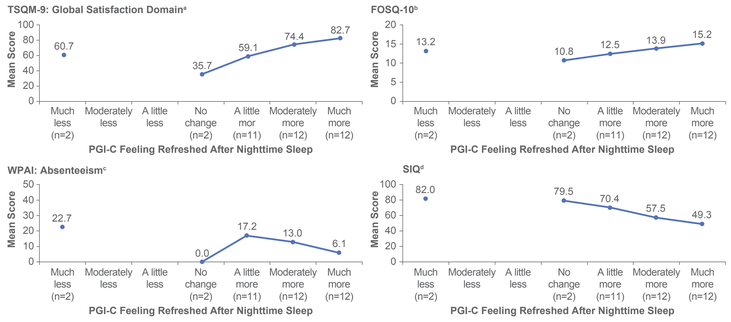
Figure 3. Associations Between PGI-C Improvements and Better PRO Scores at Enrollment

A) Improvements in Daytime Sleepiness and Feeling Refreshed After Nighttime Sleep Were Consistently Associated with Better Scores on Multiple PROs

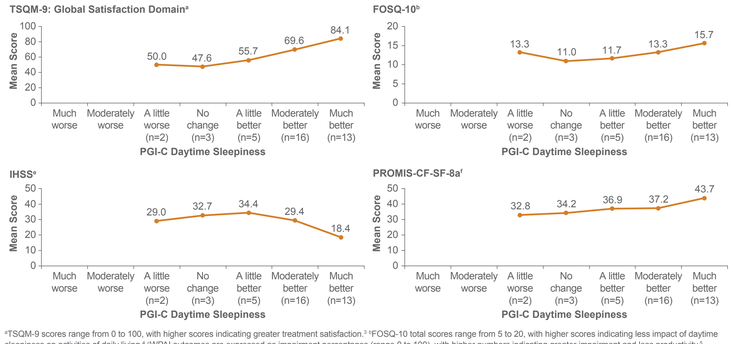
Very strong / Strong / Moderate / Weak / Minimal

		PGI-S Enrollment |r|			
		Idiopathic Hypersomnia Symptoms	Daytime Sleepiness	Nighttime Sleep Quality	Feeling Refreshed After Nighttime Sleep
Symptoms	ESS Total Score	0.314	0.538	0.320	0.408
	IHSS Total Score	0.270	0.657	0.358	0.633
	SIQ Total Score	0.288	0.431	0.275	0.645
QoL	Overall QoL PGI-C	0.589	0.623	0.415	0.800
	FOSQ-10 Total Score	0.343	0.521	0.119	0.422
	FOSQ-10 Social Outcomes subscale	0.346	0.443	0.037	0.070
	FOSQ-10 Activity Level subscale	0.269	0.480	0.229	0.277
	FOSQ-10 Vigilance subscale	0.022	0.298	0.075	0.250
	PHQ-9 Total Score	0.144	0.297	0.180	0.444
Cognition	PROMIS-CF-SF-8a T-scores	0.058	0.502	0.047	0.111
	FOSQ-10 General Productivity subscale	0.344	0.537	0.145	0.510
	FOSQ-10 item: Remembering things	0.443	0.582	0.029	0.507
	FOSQ-10 item: Concentrating	0.268	0.530	0.267	0.509
	IHSS item: Hypersomnia interferes with your intellectual functioning	0.190	0.497	0.322	0.402
	SIQ item: Have difficulty concentrating	0.322	0.589	0.417	0.486
	SIQ item: Find that you think more slowly	0.280	0.269	0.073	0.590
	SIQ item: Find that you react more slowly	0.184	0.303	0.044	0.577
	SIQ item: Find that you make more mistakes/errors	0.314	0.480	0.350	0.552
	SIQ item: Have difficulty getting your thoughts together	0.208	0.325	0.243	0.442
Work Impacts (WPAI)	Absenteeism	0.163	0.343	0.325	0.396
	Presenteeism	0.157	0.310	0.112	0.278
	Overall Work Productivity Loss	0.202	0.598	0.035	0.304
	Activity Impairment	0.283	0.600	0.179	0.378
Treatment Satisfaction (TSQM-9)	Global Satisfaction	0.507	0.608	0.065	0.557
	Effectiveness	0.617	0.608	0.014	0.424
	Convenience	0.095	0.327	0.079	0.414

B) Greater Improvements in Feeling Refreshed After Nighttime Sleep Were Associated With Higher Treatment Satisfaction, QoL, and Work Productivity, and Fewer Sleep Inertia Symptoms



C) Greater Improvements in Daytime Sleepiness Were Associated With Higher Treatment Satisfaction, QoL, and Cognitive Function, and Less Severe Idiopathic Hypersomnia Symptoms



[a]TSQM-9 scores range from 0 to 100, with higher scores indicating greater treatment satisfaction.[3] [b]FOSQ-10 total scores range from 5 to 20, with higher scores indicating less impact of daytime sleepiness on activities of daily living.[4] [c]WPAI outcomes are expressed as impairment percentages (range 0 to 100), with higher numbers indicating greater impairment and less productivity.[5] [d]SIQ scores range from 21 to 105, with higher scores indicating greater frequency or severity of sleep inertia symptoms.[3] [e]IHSS scores range from 0 to 50, with higher scores indicating more severe idiopathic hypersomnia symptoms.[3] [f]PROMIS-CF-SF-8a T-scores range from 22.41 to 63.48, with higher scores indicating better cognitive function.[8]
ESS, Epworth Sleepiness Scale; FOSQ-10, 10-item Functional Outcomes of Sleep Questionnaire; IHSS, Idiopathic Hypersomnia Severity Scale; PGI-C, Patient Global Impression of Change; PHQ-9, 9-item Patient Health Questionnaire; PRO, patient-reported outcome; PROMIS-CF-SF-8a, Patient Reported Outcome Measurement Information System–Cognitive Function–Short Form–8a; QoL, quality of life; SIQ, Sleep Inertia Questionnaire; TSQM-9, 9-item Treatment Satisfaction Questionnaire for Medication; WPAI, Work Productivity and Activity Impairment.

- PGI-C improvement in feeling refreshed after nighttime sleep was very strongly correlated with improved overall QoL and less sleep inertia, strongly correlated with higher treatment satisfaction, and moderately correlated with less work absenteeism
- PGI-C improvement in daytime sleepiness was very strongly correlated with higher treatment satisfaction and lower idiopathic hypersomnia symptom severity, and strongly correlated with fewer sleep-related QoL impacts and greater cognitive function

Figure 4. Category Improvements in PGI-S Daytime Sleepiness at Weeks 12 and 24 Were Associated With Score Improvements Across Multiple PROs

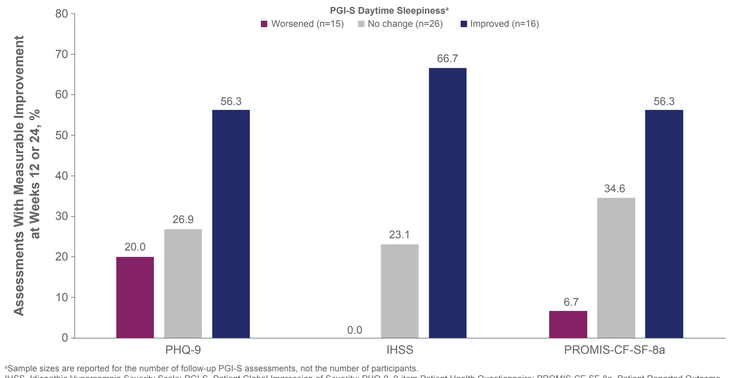
Very strong / Strong / Moderate / Weak / Minimal

		PGI-S at Weeks 12 and 24: |r|			
		Idiopathic Hypersomnia Symptoms	Daytime Sleepiness	Nighttime Sleep Quality	Feeling Refreshed After Nighttime Sleep
Symptoms	ESS Total Score	0.265	0.625	0.010	0.032
	IHSS Total Score	0.624	0.656	0.322	0.421
	SIQ Total Score	0.381	0.360	0.237	0.272
QoL	Overall QoL PGI-S	0.208	0.238	0.151	0.435
	FOSQ-10 Total Score	0.360	0.388	0.067	0.219
	FOSQ-10 Social Outcomes subscale	0.233	0.201	0.151	0.106
	FOSQ-10 Activity Level subscale	0.346	0.316	0.225	0.188
	FOSQ-10 Vigilance subscale	0.258	0.435	0.019	0.255
	PHQ-9 Total Score	0.393	0.474	0.093	0.133
Cognition	PROMIS-CF-SF-8a T-scores	0.577	0.406	0.114	0.257
	FOSQ-10 General Productivity subscale	0.456	0.322	0.118	0.198
	FOSQ-10 item: Remembering things	0.475	0.233	0.002	0.049
	FOSQ-10 item: Concentrating	0.389	0.362	0.237	0.453
	IHSS item: Hypersomnia interferes with your intellectual functioning	0.557	0.532	0.413	0.196
	SIQ item: Have difficulty concentrating	0.341	0.392	0.369	0.049
	SIQ item: Find that you think more slowly	0.133	0.128	0.153	0.003
	SIQ item: Find that you react more slowly	0.229	0.375	0.221	0.178
	SIQ item: Find that you make more mistakes/errors	0.293	0.226	0.148	0.124
	SIQ item: Have difficulty getting your thoughts together	0.492	0.454	0.268	0.099
Work Impacts (WPAI)	Absenteeism	0.260	0.138	0.400	0.176
	Presenteeism	0.212	0.269	0.430	0.175
	Overall Work Productivity Loss	0.273	0.576	0.146	0.054
	Activity Impairment	0.424	0.520	0.313	0.263
Treatment Satisfaction (TSQM-9)	Global Satisfaction	0.337	0.256	0.026	0.195
	Effectiveness	0.138	0.252	0.055	0.363
	Convenience	0.038	0.153	0.013	0.175

ESS, Epworth Sleepiness Scale; FOSQ-10, 10-item Functional Outcomes of Sleep Questionnaire; IHSS, Idiopathic Hypersomnia Severity Scale; PGI-S, Patient Global Impression of Severity; PHQ-9, 9-item Patient Health Questionnaire; PRO, patient-reported outcome; PROMIS-CF-SF-8a, Patient Reported Outcome Measurement Information System–Cognitive Function–Short Form–8a; QoL, quality of life; SIQ, Sleep Inertia Questionnaire; TSQM-9, 9-item Treatment Satisfaction Questionnaire for Medication; WPAI, Work Productivity and Activity Impairment.

- PGI-S improvements in daytime sleepiness from enrollment to weeks 12 and 24 were very strongly correlated with improvements in idiopathic hypersomnia symptom severity, and strongly correlated with improvements in depression, cognitive function, and work and activity impacts; weaker correlations for nighttime sleep quality and feeling refreshed after nighttime sleep may reflect limited variability over time among participants already taking LXB for a prolonged period

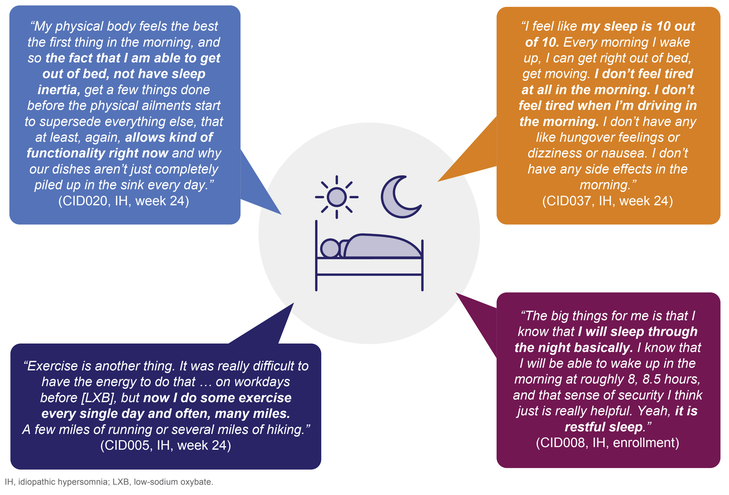
Figure 5. Category Improvements in PGI-S Daytime Sleepiness at Weeks 12 and 24 Were Associated With Measurable Improvements in Depression, Symptoms, and Cognitive Function



[a]Sample sizes are reported for the number of follow-up PGI-S assessments, not the number of participants.
IHSS, Idiopathic Hypersomnia Severity Scale; PGI-S, Patient Global Impression of Severity; PHQ-9, 9-item Patient Health Questionnaire; PROMIS-CF-SF-8a, Patient Reported Outcome Measurement Information System–Cognitive Function–Short Form–8a.

- Assessments reporting PGI-S category improvements in daytime sleepiness from enrollment to weeks 12 and 24 were more likely to show measurable improvements in outcomes including depression, idiopathic hypersomnia symptom severity, and cognitive function

Figure 6. Interview Participants Linked Nighttime Sleep Quality Improvements With Reduced Daytime Sleepiness and Fatigue, and Improved Morning Functioning



IH, idiopathic hypersomnia; LXB, low-sodium oxybate.

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Supplemental Results

Supplemental Table S1. Additional Participant Characteristics

Characteristic	Participants With Idiopathic Hypersomnia (N=40)
Age (years)	
Mean (SD)	32.7 (8.0)
Median (range)	30.5 (21–53)
Gender, n (%)	
Female	29 (72.5)
Male	11 (27.5)
Race, n (%)	
White	25 (62.5)
Black or African American	9 (22.5)
Prefer not to answer	2 (5.0)
Other	2 (5.0)
American Indian or Alaska Native	1 (2.5)
Asian	1 (2.5)
Employment, n (%)[a]	
Working full-time	26 (65.0)
Student	6 (15.0)
Seeking work opportunities	2 (5.0)
Working part-time	6 (15.0)
Homemaker	3 (7.5)
Unable to work	3 (7.5)
Number of LXB doses per night, n (%)	
1	6 (15.0)
2	34 (85.0)
Number of weeks taking LXB	
Mean (SD)	83.2 (65.9)
ESS score	
Mean (SD)	10.7 (5.3)
Other current comorbid diagnoses, n (%)[a]	
Attention deficit disorder/attention deficit hyperactivity disorder	6 (15.0)
Anxiety	21 (35.6)
Depression	18 (45.0)
Hypertension	1 (2.5)
Obesity	3 (7.5)
Obstructive sleep apnea	5 (12.5)
Periodic limb movement disorder	2 (5.0)
Restless leg syndrome	1 (2.5)
Current concomitant treatments, n (%)[a]	
Amphetamine	10 (25.0)
Armodafinil	1 (2.5)
Fluoxetine	4 (10.0)
Methylphenidate	7 (17.5)
Modafinil	3 (7.5)
Pitolisant	1 (2.5)
Sertraline	2 (5.0)
Solriamfetol	5 (12.5)
Other current treatment	4 (10.0)
None of the above[b]	16 (40.0)

[a]Response options are not mutually exclusive. [b]"None of the above" indicates participants were not taking any of the medications listed in this table; however, they may have been taking other concomitant medications.
ESS, Epworth Sleepiness Scale; LXB, low-sodium oxybate; SD, standard deviation.