

Supplementary Material

Effectiveness and Safety of Low-Sodium Oxybate in Participants With Narcolepsy: Primary Results From the DUET Study

Logan D. Schneider, MD¹; Chad M. Ruoff, MD²; David T. Plante, MD, PhD³;
Deborah A. Nichols, MS⁴; Teresa L. Steininger, PhD⁴; Douglas S. Fuller, MS⁵; M. Todd
Kirby, PhD^{5,6}; Sarah Akerman, MD^{5,*}; Jessica K. Alexander, PhD⁴; Marisa Whalen,
PharmD⁵; Alyssa Cairns, PhD⁵

¹Stanford Sleep Medicine Center, Redwood City, CA, USA; ²Mayo Clinic, Scottsdale, AZ, USA; ³Department of Psychiatry, University of Wisconsin–Madison, Madison, WI, USA; ⁴Jazz Pharmaceuticals, Palo Alto, CA, USA; ⁵Jazz Pharmaceuticals, Philadelphia, PA, USA; ⁶Department of Psychiatry & Health Behavior, Medical College of Georgia at Augusta University, Augusta, GA, USA

*Dr. Akerman is a former employee of Jazz Pharmaceuticals.

Corresponding Author

Logan D. Schneider, MD
Adjunct Clinical Associate Professor, Psychiatry and Behavioral Sciences
Stanford Sleep Medicine Center
Email: logands@gmail.com

Online Resource 1 Demographics and baseline characteristics for participants with narcolepsy who completed the study^a

Characteristic	NT1 (n=16)	NT2 (n=18)	Total (n=34)
Age (years)			
Mean (SD)	35.6 (14.2)	35.9 (14.7)	35.7 (14.2)
Median (min, max)	30.5 (20, 68)	31.0 (22, 75)	31.0 (20, 75)
Sex at birth, n (%)			
Male	3 (18.8)	6 (33.3)	9 (26.5)
Female	13 (81.3)	12 (66.7)	25 (73.5)
Gender identity, n (%)			
Male (including transgender man)	3 (18.8)	6 (33.3)	9 (26.5)
Female (including transgender woman)	13 (81.3)	12 (66.7)	25 (73.5)
Nonbinary	0	0	0
Other	0	0	0
Declined to state	0	0	0
Participant of childbearing potential, n (%)			
Yes	8 (61.5)	10 (83.3)	18 (72.0)
Race, n (%)			
White	10 (62.5)	17 (94.4)	27 (79.4)
Black or African American	3 (18.8)	1 (5.6)	4 (11.8)
American Indian or Alaska Native	0	0	0
Asian	2 (12.5)	0	2 (5.9)
Native Hawaiian or other Pacific Islander	0	0	0
Multiple	0	0	0
Unknown	1 (6.3)	0	1 (2.9)
Ethnicity, n (%)			
Hispanic or Latino	1 (6.3)	2 (11.1)	3 (8.8)
Not Hispanic or Latino	15 (93.8)	16 (88.9)	31 (91.2)
Body mass index (kg/m²)			
Mean (SD)	28.9 (6.5)	29.2 (6.0)	29.1 (6.2)
Median (min, max)	27.3 (20.0, 40.6)	27.8 (21.7, 41.2)	27.4 (20.0, 41.2)
Oxybate type at study entry^b, n (%)			
Naive ^c	11 (68.8)	15 (83.3)	26 (76.5)
Low-sodium oxybate	3 (18.8)	1 (5.6)	4 (11.8)
Sodium oxybate	1 (6.3)	2 (11.1)	3 (8.8)
Once-nightly sodium oxybate	1 (6.3)	0	1 (2.9)
Oxybate total nightly dosage at screening^d (g)			
Mean (SD)	6.5 (0.71)	7.7 (1.2)	7.0 (1.0)
Median (min, max)	6.3 (6.0, 7.5)	7.0 (7.0, 9.0)	7.0 (6.0, 9.0)
Any alerting agent, n (%)^{e,f,g}			
Amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate	2 (12.5)	5 (27.8)	7 (20.6)
Methylphenidate	3 (18.8)	1 (5.6)	4 (11.8)
Solriamfetol hydrochloride	3 (18.8)	1 (5.6)	4 (11.8)
Pitolisant hydrochloride	1 (6.3)	3 (16.7)	4 (11.8)
Bupropion hydrochloride	2 (12.5)	1 (5.6)	3 (8.8)
Lisdexamfetamine dimesylate	1 (6.3)	1 (5.6)	2 (5.9)
Dexmethylphenidate	1 (6.3)	0	1 (2.9)
Modafinil	1 (6.3)	0	1 (2.9)

^aCompleter analysis set includes all participants who enrolled in the study, took their prescribed LXB regimen for ≥ 1 night after the BL period, completed the SDP, and completed the PSG EOT visit.

^bParticipants taking oxybate at study entry included n=4 (NT1) and n=3 (NT2).

^cNo oxybate use within 2 weeks of entering the study.

^dFor the 7 participants who were taking an oxybate at screening and prior to washout.

^eParticipants could have been taking multiple different alerting medications.

^fIt is not known whether these agents were prescribed for excessive sleepiness, narcolepsy, and/or another condition.

^gConcomitant medications had a stop date on or after date of first dose of study intervention or were ongoing.

BL, baseline; EOT, end of treatment; LXB, low-sodium oxybate; max, maximum; min, minimum; NT1, narcolepsy type 1; NT2, narcolepsy type 2; PSG, polysomnography; SD, standard deviation.