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Effectiveness and Safety of Low-Sodium Oxybate Dosages >9 Grams in Study Participants With Narcolepsy

DUET STUDY 407

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Introduction

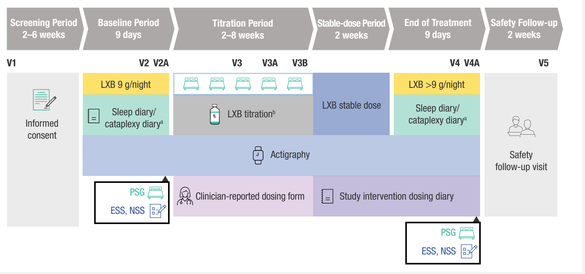
- Low-sodium oxybate (LXB, Xywav®) is approved by the US Food and Drug Administration to treat excessive daytime sleepiness (EDS) or cataplexy in patients ≥7 years of age with narcolepsy and for the treatment of idiopathic hypersomnia in adults[1-4]
- The recommended dosage range is 6 g to 9 g/night, gradually titrated based on efficacy and tolerability[1]
- Some patients may achieve better responses with unequal doses at bedtime and 2.5 to 4 hours later[1]
- Dosages higher than 9 g/night have not been studied and ordinarily should not be administered[1]
  - Real-world data from the Nexus Narcolepsy Registry reported that 4.1% of patients taking sodium oxybate were taking a dosage of >9 g/night[5]
- Jazz DUET (**D**evelop hypersomnia **U**nderstanding by **E**valuating low-sodium oxybate **T**reatment) was a phase 4, prospective, multicenter, single-arm, multiple-cohort, open-label study (NCT05875974) of LXB treatment in participants with narcolepsy (type 1 [NT1] or type 2 [NT2]) or idiopathic hypersomnia
- DUET included a third cohort in which narcolepsy participants currently utilizing 9 g of oxybate could have their total nightly dosage optimized up to 12 g (twice-nightly; maximum 4.5 g for second dose)

Objective

- To evaluate the effectiveness and safety of LXB in participants with narcolepsy taking a dosage of >9 g/night from an intermediate dataset as of November 20, 2024*

Methods

Figure 1. Study Design



[a]Cataplexy diary in narcolepsy type 1 only. [b]Weekly titration visits with a dose escalation were performed as an overnight PSG visit for safety monitoring; visits without a dose escalation could be via teleconference. Titration could take between 2 and 8 weeks. Visit 3 occurred on titration day 14. Additional in-clinic visits were scheduled for day 35 (visit 3A) and day 56 (visit 3B), as needed. Investigator could optimize participant dosage and move participant to SDP at visit 3, 3A, or 3B but not during intervening weekly teleconferences.
EOT, end of treatment; ESS, Epworth Sleepiness Scale; LXB, low-sodium oxybate; NSS, Narcolepsy Severity Scale; PSG, polysomnography; SDP, stable-dose period; V, visit.

- DUET included a screening period, a 9-day baseline (BL) period on LXB 9 g/night (8 days of daily assessments ending with an overnight BL polysomnography [PSG] with additional assessments, followed by an optional overnight pharmacokinetic [PK] visit), a 2- to 8-week LXB titration period (with an overnight PSG visit for all dose escalations, for safety monitoring), a 2-week stable-dose period (SDP), a 9-day end-of-treatment (EOT) period while participants were taking their optimized stable dose of LXB (daily assessments ending with an overnight EOT PSG with additional assessments, followed by an optional overnight PK visit), and a 2-week safety follow-up; PK visits were conducted at select study sites at V2A and V4A

Figure 2. Key Inclusion and Exclusion Criteria

Key Inclusion Criteria

- Adults aged 18 to 75 with a primary diagnosis of NT1 or NT2[a]
- Stable use of concomitant anticataplectics or alerting agents[b] allowed
- On 9 g of LXB at screening or titrated up to 9 g in the main study (narcolepsy cohort), with investigator assessment of potential benefit from LXB dosage of >9 g

Key Exclusion Criteria

- Untreated or inadequately treated OSA at baseline PSG (AHI >10)[c]
- History/presence of:
  - Unstable or clinically significant medical condition
  - Behavioral/psychiatric, neurologic disorder[d]

[a]Meeting the *International Classification of Sleep Disorders – Third Edition* or *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* criteria. [b]Alerting agents were defined as stimulants or wake-promoting agents. [c]Defined as AHI >10, with hypopnea definition including a ≥4% desaturation as per Rule 1B of *The AASM Manual for the Scoring of Sleep and Associated Events*.[6] [d]As determined by the investigator.
AHI, apnea-hypopnea index; AASM, American Academy of Sleep Medicine; DSM-5, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*; ICSD-3, *International Classification of Sleep Disorders – Third Edition*; NT1, narcolepsy type 1; NT2, narcolepsy type 2; OSA, obstructive sleep apnea; PSG, polysomnography.

- Participants could enter the >9 g narcolepsy cohort 1 of 2 ways:
  - Potential participants with narcolepsy taking LXB at a dosage of 9 g/night at screening who, in the opinion of the investigator, would likely benefit from continued titration to dosages >9 g/night, and who met eligibility criteria were eligible to enter the >9 g cohort
  - Participants with narcolepsy already enrolled in the main study, who had titrated up to 9 g and who, in the opinion of the investigator could benefit from a higher LXB dose, could transfer to the >9 g cohort
- Participants adequately treated for OSA (AHI ≤10) were eligible and asked to maintain any treatment regimen (eg, PAP, oral appliance) for the entirety of the study.
- There was no ESS score eligibility requirement at screening for the >9 g cohort

LXB Titration Requirements

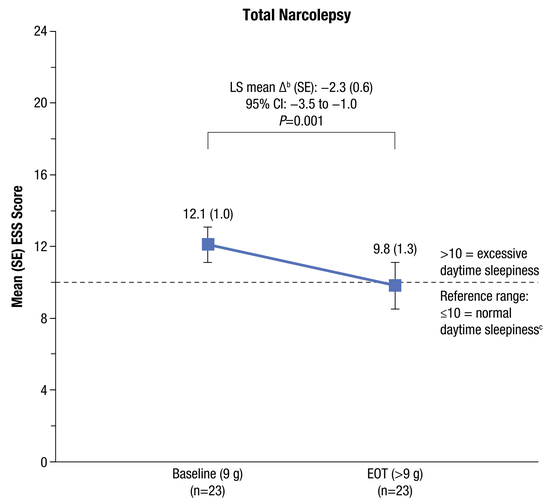
Investigators titrated LXB to an optimal dosage for participants in the >9 g cohort under the following requirements:

- The first night for all LXB dose escalations above 9 g were conducted in the sleep laboratory clinic with PSG and appropriate in-clinic safety monitoring
- Each dose-escalation step during titration was limited to 0.5 g/night/week, up to a maximum of 12 g nightly
- All participants took twice-nightly LXB
  - The first nightly maximal dose was 7.5 g
  - The second nightly maximal dose was 4.5 g, and was administered approximately 4 hours after the first dose

- Key endpoints were change in Epworth Sleepiness Scale (ESS) score from BL to EOT and change in Narcolepsy Severity Scale (NSS) score from BL to EOT (the NSS-2 version, excluding questions on cataplexy, was administered to participants with NT2)
- Safety endpoints included incidence and severity of treatment-emergent adverse events (TEAEs); Columbia-Suicide Severity Rating Scale (C-SSRS); and sleep-related respiratory assessments measured by PSG, including apnea-hypopnea index (AHI), the number of central apnea events, mean oxygen saturation (SpO_2), and the percentage of total sleep time (TST) spent with SpO_2 <90%
- The safety analysis set includes all participants who enrolled in the study and took their prescribed LXB regimen for ≥1 night after the BL period (for this partial cohort, N=24); the completer 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 (n=23, as of the November 20, 2024, datacut*)
  - One participant completed screening but discontinued prior to entering the intervention period due to physician decision
- The final sample size for this cohort was expected to be ≥40 completers
- Observed values and change from BL were summarized as continuous variables (mean, standard error, quartiles, minimum, maximum); no formal hypothesis testing was planned for the >9 g cohort
  - Least-squares (LS) mean differences were calculated using mixed model with repeated measures of change from BL to EOT, adjusted for the BL value
  - Nominal *P* values from a post-hoc analysis are reported, and are not controlled for multiplicity

*Intermediate analysis from November 20, 2024, datacut; data were analyzed in December 2024.

Figure 3. ESS Scores Improved From BL to EOT in Participants Taking >9 g/night LXB[a]



[a]Completer analysis set. [b]Difference between EOT and baseline. *P* value is nominal. [c]Established categories consider scores up to 10 normal.[7] The MCID for ESS was defined as 2 points according to an AASM systematic review and meta-analysis.[8]
AASM, American Academy of Sleep Medicine; CI, confidence interval; EOT, end of treatment; ESS, Epworth Sleepiness Scale; LS, least squares; LXB, low-sodium oxybate; MCID, minimal clinically important difference; SE, standard error.

- Mean (SE) ESS score at BL was 12.1 (1.0), indicating EDS despite treatment with LXB 9 g/night and the use of alerting agents by 75% of participants; at EOT, this decreased to 9.8 (1.3)
  - For reference, at EOT in the main DUET narcolepsy cohort (optimized up to 9 g), mean (SE) ESS score was 8.6 (1.0) [see **Poster 393**]
- Mean (SE) ESS scores also decreased from BL to EOT in participants with NT1 (13.3 [1.5] to 11.9 [1.8]; LS mean [95% CI] change, −1.4 [−3.0, 0.1]) and NT2 (10.2 [1.1] to 6.6 [1.1]; LS mean [95% CI] change, −3.6 [−5.5, −1.7])

Table 1. Demographics and Baseline Characteristics[a]

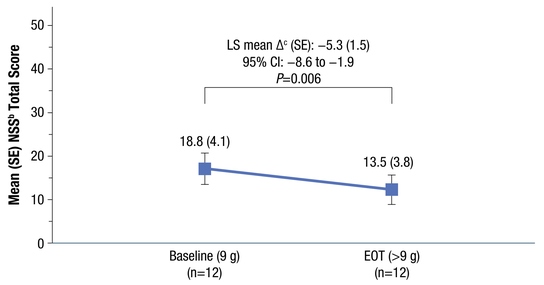
Characteristic	NT1 (n=14)	NT2 (n=10)	Total Narcolepsy Cohort (N=24)
Age (years)			
Mean (SD)	39.4 (11.8)	38.2 (10.5)	38.9 (11.0)
Median (min, max)	39.0 (18, 59)	37.5 (20, 59)	38.5 (18, 59)
Sex at birth, n (%)			
Male	5 (35.7)	4 (40.0)	9 (37.5)
Female	9 (64.3)	6 (60.0)	15 (62.5)
Gender identity, n (%)			
Male (including transgender man)	5 (35.7)	4 (40.0)	9 (37.5)
Female (including transgender woman)	9 (64.3)	6 (60.0)	15 (62.5)
Nonbinary	0	0	0
Other	0	0	0
Declined to state	0	0	0
Participant of childbearing potential, n (%)[b]	6 (66.7)	4 (66.7)	10 (66.7)
Race, n (%)			
White	12 (85.7)	6 (60.0)	18 (75.0)
Black or African American	1 (7.1)	3 (30.0)	4 (16.7)
American Indian or Alaska Native	0	0	0
Asian	1 (7.1)	0	1 (4.2)
Native Hawaiian or other Pacific Islander	0	0	0
Multiple[c]	0	1 (10.0)	1 (4.2)
Ethnicity, n (%)			
Hispanic or Latino	1 (7.1)	0	1 (4.2)
Not Hispanic or Latino	13 (92.9)	10 (100.0)	23 (95.8)
Body mass index (kg/m²)			
Mean (SD)	33.5 (6.3)	31.7 (12.0)	32.7 (8.9)
Median (min, max)	32.8 (22.1, 42.7)	27.4 (21.4, 58.7)	31.4 (21.4, 58.7)
Diagnosed sleep apnea,[d] n (%)	5 (35.7)	2 (20.0)	7 (29.2)
Transferred from main narcolepsy cohort (≤9 g/night)	9 (64.3)	4 (40.0)	13 (54.2)

[a]Safety analysis set. [b]Percent calculated only for female sex at birth. [c]Participant reported >1 race. [d]Per medical history at screening V1.
Max, maximum; min, minimum; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SD, standard deviation.

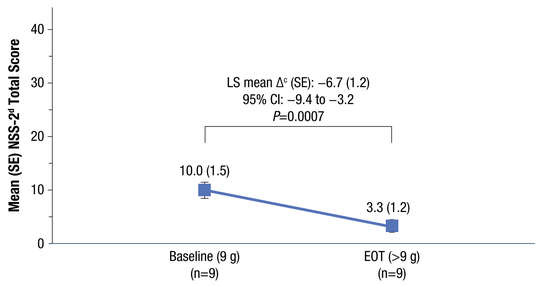
- As of November 20, 2024, 24 participants took LXB in the >9 g cohort (mean [SD] age: 38.9 [11.0] years)
  - Most were female (62.5%) and White (75.0%)
  - Mean (SD) body mass index was 32.7 (8.9); 29.2% of participants had a comorbid sleep apnea
  - Demographics and baseline characteristics of participants who transferred from the main narcolepsy cohort and of those who entered the >9 g cohort directly and are included in the completer analysis set are available through the QR code in the corner

Figure 4. Participants Taking >9 g/night Reported Improvements in Narcolepsy Symptoms on the NSS (A) and NSS-2 (B)[a]

A) NSS (Participants With NT1)[b]



B) NSS-2 (Participants With NT2)[d]



[a]Completer analysis set. [b]For the NSS, levels of severity are as follows: Very Severe (43–57), Severe (29–42), Moderate (15–28), Mild (0–14).[9] [c]Difference between EOT and baseline. *P* value is nominal. [d]For the NSS-2, the MCID between untreated and treated patients was 3.35 with the Cohen effect size and 3.22 with the empirical rule effect size according to a longitudinal study (n=26).[10]
EOT, end of treatment; LS, least squares; LXB, low-sodium oxybate; Max, maximum; MCID, minimal clinically important difference; NSS, Narcolepsy Severity Scale Score; NSS-2, Narcolepsy Severity Scale-2; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SE, standard error.

Table 2. Mean Nightly LXB Dosage During Stable-Dose Period[a]

LXB Dose, g	NT1 (n=14)	NT2 (n=10)	Total Narcolepsy Cohort (N=23[a])
Overall total nightly LXB dosage			
Mean (SD)	11.0 (1.1)	11.5 (0.9)	11.2 (1.1)
Median (min, max)	11.3 (9.0,[b] 12.0)	12.0 (9.7, 12.0)	12.0 (9.0, 12.0)
Twice-nightly LXB dosage[c] (n=23)			
First nightly LXB dose			
Mean (SD)	6.6 (1.1)	7.0 (0.9)	6.8 (1.0)
Median (min, max)	7.3 (4.5, 7.5)	7.5 (5.2, 7.5)	7.5 (4.5, 7.5)
Second nightly LXB dose			
Mean (SD)	4.4 (0.3)	4.5 (0)	4.4 (0.2)
Median (min, max)	4.5 (3.5, 4.5)	4.5 (4.5, 4.5)	4.5 (3.5, 4.5)

[a]Includes all participants from the safety analysis set who reached the stable-dose period. [b]One participant down-titrated to 9.0 mg due to an AE (nausea). [c]All participants took LXB twice-nightly.
AE, adverse event; LXB, low-sodium oxybate; max, maximum; min, minimum; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SD, standard deviation.

- Once a participant reached an optimized dosage based on investigator judgment, they continued this dosage as a stable regimen during the SDP and EOT periods
- A total LXB dosage of 12 g/night was reached by 60.9 (14/23) of participants

Table 3. Concomitant Alerting Medications[a,b]

ATC Level 4 Term, n (%) Preferred Term, n (%)	NT1 (n=14)	NT2 (n=10)	Total Narcolepsy Cohort (N=24)
Participants taking a concomitant alerting agent,[c,d] n (%)	10 (71.4)	8 (80.0)	18 (75.0)
Centrally acting sympathomimetics			
Amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate	5 (35.7)	3 (30.0)	8 (33.3)
Solriamfetol hydrochloride	2 (14.3)	1 (10.0)	3 (12.5)
Armodafinil	1 (7.1)	1 (10.0)	2 (8.3)
Methylphenidate	1 (7.1)	1 (10.0)	2 (8.3)
Amphetamine sulfate	0	1 (10.0)	1 (4.2)
Lisdexamfetamine dimesylate	1 (7.1)	0	1 (4.2)
Other antidepressants			
Bupropion hydrochloride	0	1 (10.0)	1 (4.2)
Other nervous system drugs			
Pitolisant hydrochloride	2 (14.3)	3 (30.0)	5 (20.8)

[a]Safety analysis set. [b]Participants could have been taking multiple different alerting medications. [c]It is not known whether these agents were prescribed for excessive sleepiness, narcolepsy, idiopathic hypersomnia, or another condition. [d]Concomitant medications were started prior to the first dose of LXB and were ongoing throughout the study or could have been stopped after the first dose of LXB. Concomitant medications for transfer participants were programmatically imputed from the main narcolepsy cohort if the medication was ongoing.
ATC, anatomical therapeutic chemical; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- At study entry, 18 participants (75.0%) were taking alerting agents

Table 4. Respiratory Assessment Measures Showed Minimal Changes From BL to EOT in Participants Taking >9 g/night LXB[a]

Characteristic	NT1 (n=14) BL (9 g)	NT1 (n=14) EOT (>9 g)	NT2 (n=9) BL (9 g)	NT2 (n=9) EOT (>9 g)	Total Narcolepsy Cohort (N=23) BL (9 g)	Total Narcolepsy Cohort (N=23) EOT (>9 g)
Apnea-hypopnea index score (full night; events/hour)						
Mean (SE)	2.7 (1.1)	1.1 (0.2)	1.3 (0.3)	1.8 (0.5)	2.2 (0.7)	1.4 (0.2)
LS mean Δ[b] (SE)	−1.1 (0.3)		−0.3 (0.4)		−0.8 (0.3)	
95% CI	−1.8 to −0.4		−1.3 to −0.3		−1.3 to −0.3	
Central apnea events (full night; number)						
Mean (SE)	8.5 (7.3)	3.4 (1.3)	3.3 (1.1)	6.0 (2.5)	6.5 (4.4)	4.4 (1.3)
LS mean Δ[b] (SE)	−3.2 (1.6)		−0.3 (2.0)		−2.0 (1.3)	
95% CI	−6.6 to 0.2		−4.4 to 3.9		−4.7 to 0.6	
Mean SpO_2 (full night; %)						
Mean (SE)	95.2 (0.4)	95.6 (0.2)	97.1 (0.4)	96.3 (0.2)	96.0 (0.4)	95.9 (0.2)
LS mean Δ[b] (SE)	−0.1 (0.2)		0.1 (0.3)		−0.04 (0.2)	
95% CI	−0.6 to 0.4		−0.5 to 0.7		−0.4 to 0.3	
Percentage of total sleep time spent with SpO_2 <90% (full night; %)						
Mean (SE)	0.9 (0.5)	0.02 (0.01)	0.02 (0.01)	0.08 (0.07)	0.6 (0.3)	0.04 (0.03)
LS mean Δ[b] (SE)	−0.5 (0.04)		−0.5 (0.05)		−0.5 (0.03)	
95% CI	−0.6 to −0.5		−0.6 to −0.4		−0.6 to −0.5	

[a]Completer analysis set. [b]Difference between EOT and BL.
BL, baseline; CI, confidence interval; EOT, end of treatment; LS, least squares; LXB, low-sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SE, standard error; SpO_2, oxygen saturation.

- No participants taking LXB dosages >9 g/night had AHI >10 during the EOT PSG

Table 5. Treatment-Emergent Adverse Events[a]

TEAEs occurring in ≥5% of participants, n (%)	NT1 (n=14)	NT2 (n=10)	Total Narcolepsy Cohort (N=24)
Vomiting	2 (14.3%)[b]	2 (20.0%)[b]	4 (16.7%)
Nausea	1 (7.1%)[b]	2 (20.0%)[b]	3 (12.5%)
Enuresis	3 (21.4%)[c]	0	3 (12.5%)
Headache	3 (21.4%)[c]	0	3 (12.5%)
Hypotension	2 (14.3%)[d]	1 (10.0%)[b]	3 (12.5%)
Alanine aminotransferase increased	1 (7.1%)[b]	1 (10.0%)[b]	2 (8.3%)
Diarrhea	2 (14.3%)	0	2 (8.3%)
Fall	1 (7.1%)[b]	1 (10.0%)	2 (8.3%)
Pollakiuria	1 (7.1%)[b]	1 (10.0%)[b]	2 (8.3%)
Somnolence	1 (7.1%)[b]	1 (10.0%)[b]	2 (8.3%)
Upper respiratory tract infection	2 (14.3%)	0	2 (8.3%)

[a]Safety analysis set. [b]TEAE (n=1) considered treatment-related. [c]TEAE (n=3) considered treatment-related. [d]TEAE (n=2) considered treatment-related.
NT1, narcolepsy type 1; NT2, narcolepsy type 2; TEAE, treatment-emergent adverse event.

- 70.8% of participants reported a TEAE
- TEAEs were mostly mild or moderate in severity; no serious TEAEs were reported
  - Two severe TEAEs occurred (NT1, hypnagogic hallucinations; NT2, nausea)
  - One TEAE (nausea) led to discontinuation
- No suicidal ideation/behaviors were reported on the C-SSRS

Conclusions

- In this intermediate analysis (datacut: November 20, 2024), participants with narcolepsy treated with an LXB dosage >9 g/night (mean [SD] 11.2 [1.1] g/night) experienced additional symptom benefit compared to treatment with 9 g/night (at baseline), with reductions in ESS and NSS scores
- Limitations include the open-label design and lack of a control cohort, which limits the ability to causally attribute the findings to LXB; the study cohort was ongoing at the time of this intermediate analysis
- No respiratory safety signals were observed in this study with LXB treatment at dosages >9 g/night
- Overall, TEAEs were consistent with the known safety profile of LXB at dosages ≤9 g/night, supporting individualized treatment
- Final database lock for the >9 g cohort occurred in April 2025, with a total of N=43 completers

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Demographics and Baseline Characteristics of Participants Who Transferred From the Main DUET Cohort (≤9 g/night) and Those Who Entered the >9 g/night Cohort Directly[a]

Characteristic	Non-Transfer Participants n=13	Transfer Participants[b] n=10
Age (years)		
Mean (SD)	44.5 (8.98)	33.5 (9.28)
Median (min, max)	43.0 (33, 59)	32.5 (18, 47)
Sex at birth, n (%)		
Male	6 (46.2)	3 (30.0)
Female	7 (53.8)	7 (70.0)
Gender identity, n (%)		
Male (including transgender man)	6 (46.2)	3 (30.0)
Female (including transgender woman)	7 (53.8)	7 (70.0)
Nonbinary	0	0
Other	0	0
Declined to state	0	0
Participant of childbearing potential, n (%)[c]	2 (28.6)	7 (100)
Race, n (%)		
White	9 (69.2)	9 (90.0)
Black or African American	3 (23.1)	1 (10.0)
American Indian or Alaska Native	0	0
Asian	1 (7.7)	0
Native Hawaiian or other Pacific Islander	0	0
Multiple[d]	0	0
Ethnicity, n (%)		
Hispanic or Latino	1 (7.7)	0
Not Hispanic or Latino	12 (92.3)	10 (100)
Body mass index (kg/m^2)		
Mean (SD)	32.8 (9.8)	33.1 (8.6)
Median (min, max)	31.0 (22.0, 58.7)	34.8 (21.4, 43.1)
Time on oxybate treatment before entering study (months)		
Mean (SD)	25.7 (33.4)	17.7 (28.3)
Median (min, max)	12.5 (1.0, 114.4)	2.7 (1.2, 84.1)

[a]Completer analysis set. [b]Of the 13 transfer participants, 1 screen failed and 1 met eligibility criteria, but due to an adverse event, never escalated dose >9.0 grams. [c]Percent calculated only for female sex at birth. [d]Participant reported >1 race.