



Vibrance-1 Arixorexton Phase 2 Study in Patients with Narcolepsy Type 1

September 8, 2025



World Sleep Congress | September 5 – 10, 2025

Forward-Looking Statements

Certain statements set forth in this presentation constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the potential therapeutic and commercial value of alixorexton (formerly referred to as ALKS 2680) and the company’s expectations regarding the alixorexton development program. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks, assumptions and uncertainties. These risks, assumptions and uncertainties include, among others: whether initial clinical results for alixorexton will be predictive of results of future stages of ongoing clinical studies, future clinical studies or real-world results; whether ongoing or future clinical studies for alixorexton will be initiated or completed on expected timelines or at all; whether alixorexton could be shown to be ineffective or unsafe; potential changes in the cost, scope and duration of the alixorexton development program; and those risks, assumptions and uncertainties described under the heading “Risk Factors” in the company’s Annual Report on Form 10-K for the year ended Dec. 31, 2024 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission (“SEC”), which are available on the SEC’s website at www.sec.gov, and on the company’s website at www.alkermes.com in the ‘Investors – SEC filings’ section. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation.

Vibrance-1 Phase 2 Study of Arixorexton in Patients With Narcolepsy Type 1



- ▶ Once-daily arixorexton demonstrated new, potential best-in-class features across a range of doses
- ▶ Compelling therapeutic benefit; statistically significant effect on excessive daytime sleepiness and significant improvements in overall disease severity, fatigue and cognition
- ▶ Generally well-tolerated profile at all doses
- ▶ Alkermes plans to rapidly initiate global phase 3 program

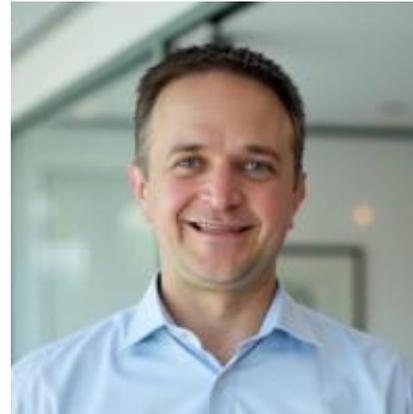
Today's Speakers



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Chief Executive Officer



Craig Hopkinson, M.D.
*Executive Vice President,
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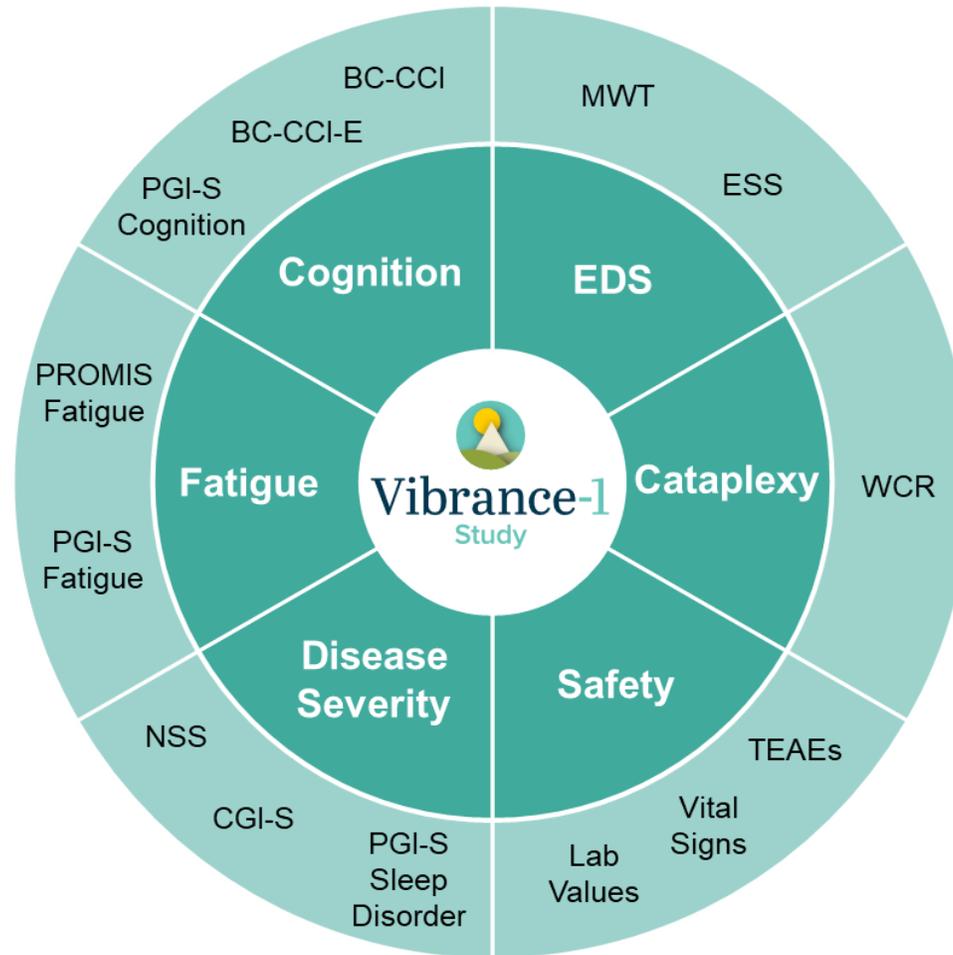


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Vibrance-1 Examined the Effects of Alixorexton on Measures Relevant to the Clinical Needs of Patients With NT1



BC-CCI = British Columbia Cognitive Complaints Inventory; BC-CCI-E = British Columbia Cognitive Complaints Inventory – Expanded; CGI-S = Clinical Global Impression of Severity; ESS = Epworth Sleepiness Scale; MWT = Maintenance of Wakefulness Test; NSS = Narcolepsy Severity Scale; PGI-S = Patient Global Impression of Severity; PROMIS = Patient-Reported Outcomes Measurement Information System; TEAE = treatment-emergent adverse event; WCR = weekly cataplexy rate.

Vibrance-1 Phase 2 Study: 6-Week Double-blind Period Followed by an Open-label Extension Period With Dosing Flexibility

Inclusion criteria

NT1 patients (ICSD-3-TR) with residual EDS and cataplexy

- Age 18 to ≤ 70 years
- BMI ≥ 18 and ≤ 40 kg/m²
- HLA-DQB1*06:02-positive or hypocretin-1 CSF ≤ 110 pg/mL
- Washout from narcolepsy medications ≥ 14 days

Exclusion criteria

Significant comorbid conditions:

- Sleep disorders/disturbed sleep
- Cardiovascular disease
- Psychiatric or substance use disorder
- Other chronic conditions (e.g., diabetes, hepatic/renal disease)

6-Week Randomized Double-Blind Treatment Period

1:1:1:1

4 mg Alixorexton

6 mg Alixorexton

8 mg Alixorexton

Placebo

Weeks

0 2 4 6

Oral, once daily

Optional Open-label Extension 7 Weeks

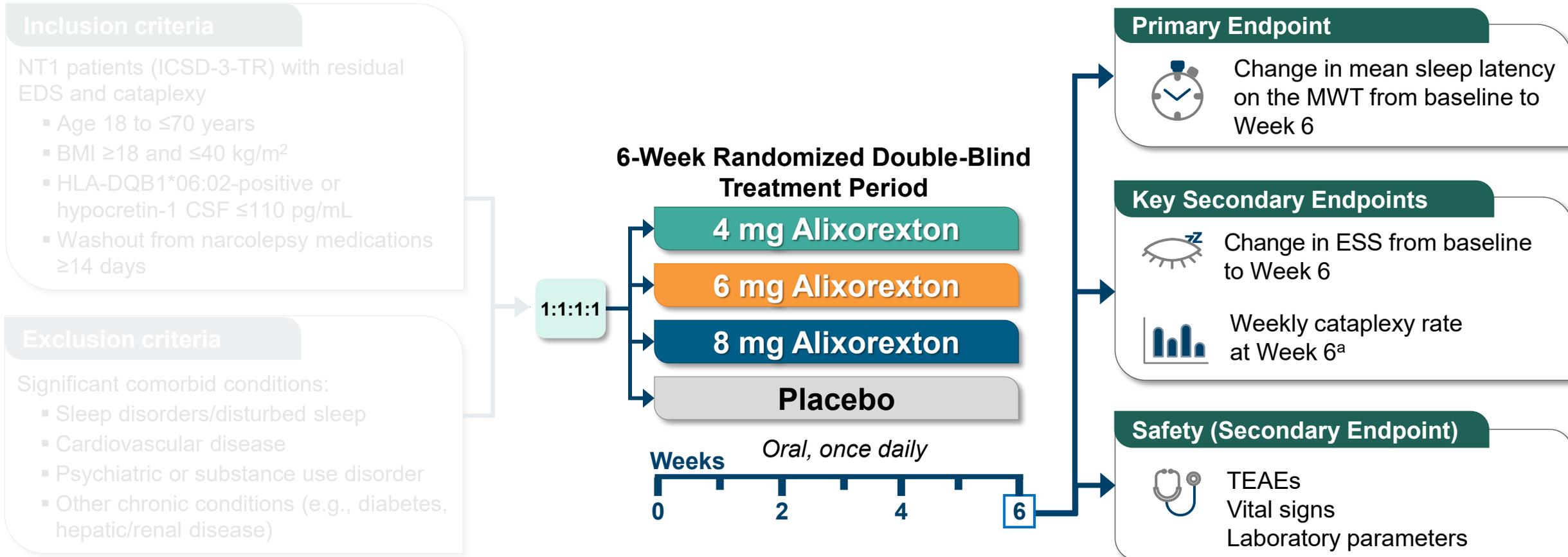
Patients receive alixorexton (adjusted dosing^a)

Safety Follow-up 2 Weeks

ALKS 2680-301
Phase 2/3
Long-term
Extension Study

^aAll patients in the open-label extension period start with 6 mg alixorexton. Dose adjustment possible (up or down) during the first 2 weeks of the optional open-label extension period. BMI = body mass index; CSF = cerebrospinal fluid; EDS = Excessive Daytime Sleepiness; ICSD-3-TR = International Classification of Sleep Disorders, third edition, text revision; NT1 = narcolepsy type 1.

Primary Efficacy and Secondary Endpoints Were Evaluated at the End of the 6-week Double-blind Treatment Period



^aWeekly cataplexy rate at Week 6 was derived from patients' cataplexy diaries over Weeks 5 and 6.

BMI = body mass index; CSF = cerebrospinal fluid; EDS = Excessive Daytime Sleepiness; ESS = Epworth Sleepiness Scale; ICSD-3-TR = International Classification of Sleep Disorders, third edition, text revision; MWT = Maintenance of Wakefulness Test; NT1 = narcolepsy type 1; TEAE = treatment-emergent adverse event.

Vibrance-1 Phase 2 Study: Baseline Characteristics and Study Disposition

Alixorexton once daily

	Placebo (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)	Total (N=92)
Disease Severity					
Mean Sleep Latency on MWT (minutes), Mean (SD)	2.8 (3.1)	3.3 (3.3)	3.4 (3.2)	2.8 (2.9)	3.1 (3.1)
ESS , Mean (SD)	18.7 (2.7)	18.2 (2.5)	18.5 (3.1)	18.7 (4.0)	18.5 (3.1)
WCR^a Mean (SD)	26.6 (29.9)	37.8 (53.5)	16.8 (9.8)	23.0 (17.3)	26.11 (32.6)
Median	14.0	20.5	15.1	15.9	16.8
[min, max]	[1.6, 121.0]	[4.7, 255.0]	[5.0, 49.0]	[1.4, 67.5]	[1.4, 255.0]
NSS^b Mean (SD)	32.7 (7.4)	32.5 (9.1)	29.0 (8.4)	30.9 (9.5)	31.3 (8.6)
Patient Disposition					
Completed Week 6 visit , n (%)	23 (100)	23 (100)	22 (100)	23 (96)	91 (99)

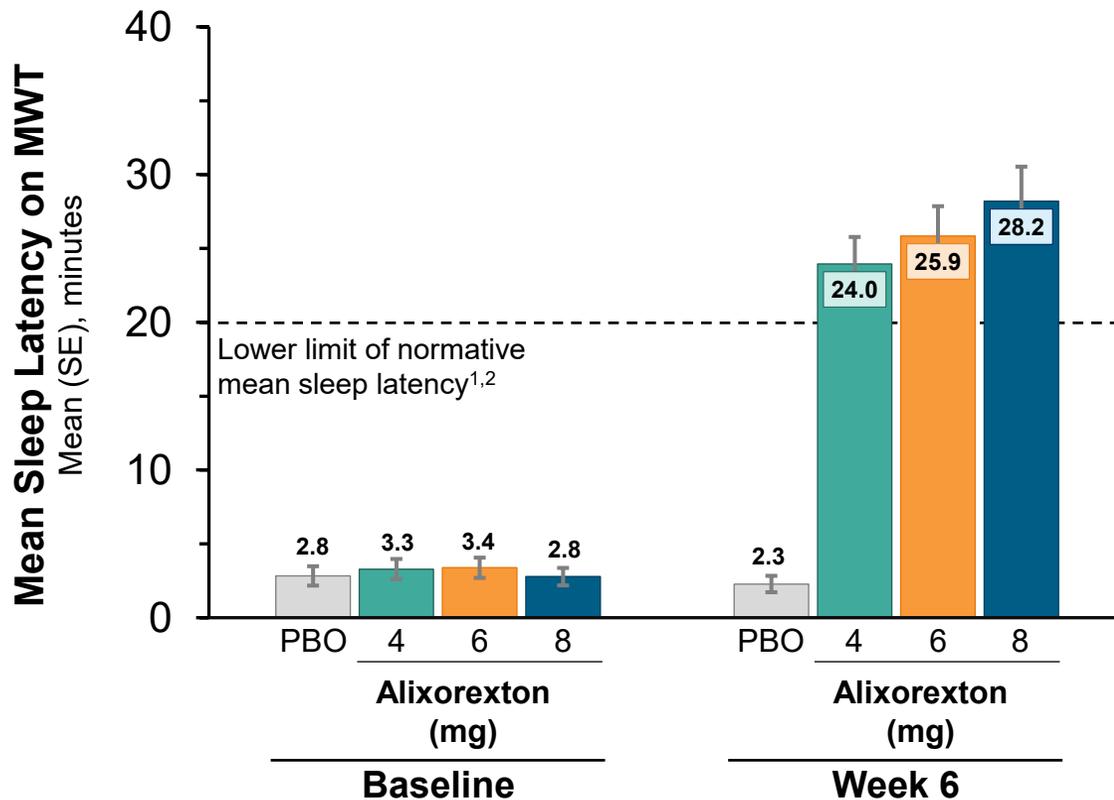
Demographics

Age	33.5 years (mean)
Sex	Females 62%
Race	White 38% Black 9% NR ^c 46%
BMI	28.4 kg/m ² (mean)

^aBaseline WCR calculated as the average weekly cataplexy rate over 2 weeks prior to first dose of study drug. ^bNo baseline NSS available for 1 patient in the placebo group and 1 patient in the 6 mg alixorexton group. ^cRace not reported in European Union member countries per regulations.

BMI = body mass index; ESS = Epworth Sleepiness Scale; MWT = Maintenance of Wakefulness Test; NR = not reported; NSS = Narcolepsy Severity Scale; SD = standard deviation; WCR = weekly cataplexy rate.

Primary Endpoint: Mean Sleep Latency on the MWT Showed Alixorexton Achieved Normative Wakefulness at All Doses



Primary Endpoint Analysis at Week 6

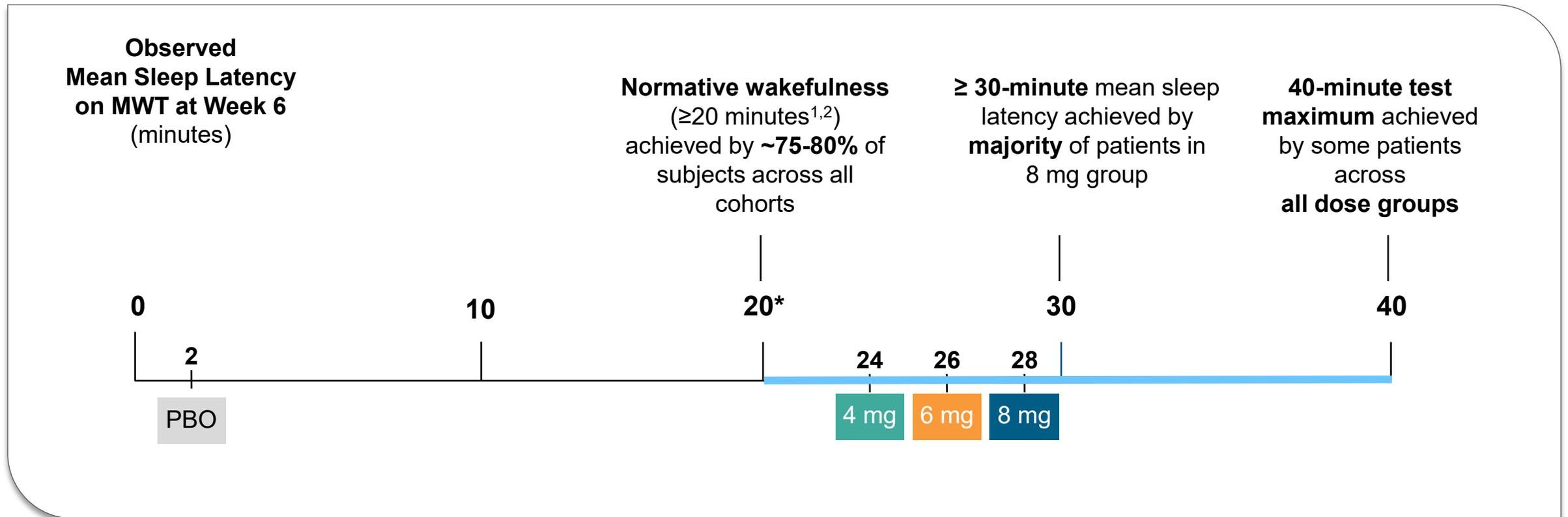
Change from baseline at Week 6 (minutes) ^a	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
LSM	-0.6	21.6	23.5	25.5
(95% CI of LSM)	(-4.5, 3.3)	(17.7, 25.6)	(19.4, 27.6)	(21.4, 29.5)
LSM difference vs PBO		22.2	24.1	26.0
(95% CI of LSM difference)		(17.2, 27.2)	(19.0, 29.1)	(21.0, 31.0)
P value		0.01	<0.0001	<0.0001
(Adjusted for multiplicity)				

^aANCOVA model. Missing data were imputed using multiple imputation.

1. Krahn LE, et al. *J Clin Sleep Med*. 2021;17(12):2489-2498. 2. Doghramji K, et al. *Electroencephalogr Clin Neurophysiol*. 1997;103(5):554-562.

ANCOVA = analysis of covariance; CI = confidence interval; LSM = least squares mean; MWT = Maintenance of Wakefulness Test; PBO = placebo; SE = standard error; WCR = weekly cataplexy rate.

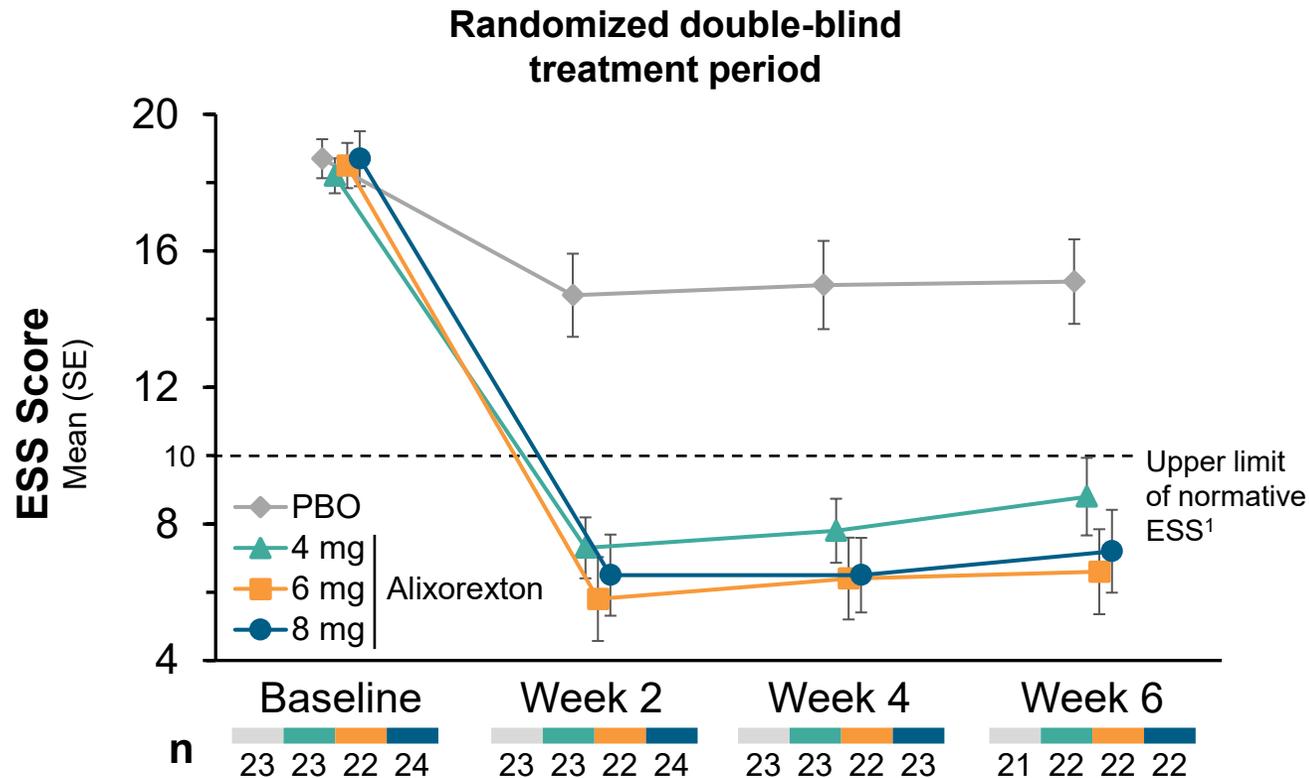
MWT Results Highlight That Patients Differ in Physiological Response and Underscore Importance of Range of Doses



MWT = Maintenance of Wakefulness Test; *Lower limit of normative mean sleep latency^{1,2}

1. Krahn LE, et al. *J Clin Sleep Med*. 2021;17(12):2489-2498. 2. Doghramji K, et al. *Electroencephalogr Clin Neurophysiol*. 1997;103(5):554-562.

Key Secondary Endpoint: Epworth Sleepiness Scale Showed Alixorexton Achieved Normative Wakefulness at All Doses



Key Secondary Endpoint Analysis at Week 6

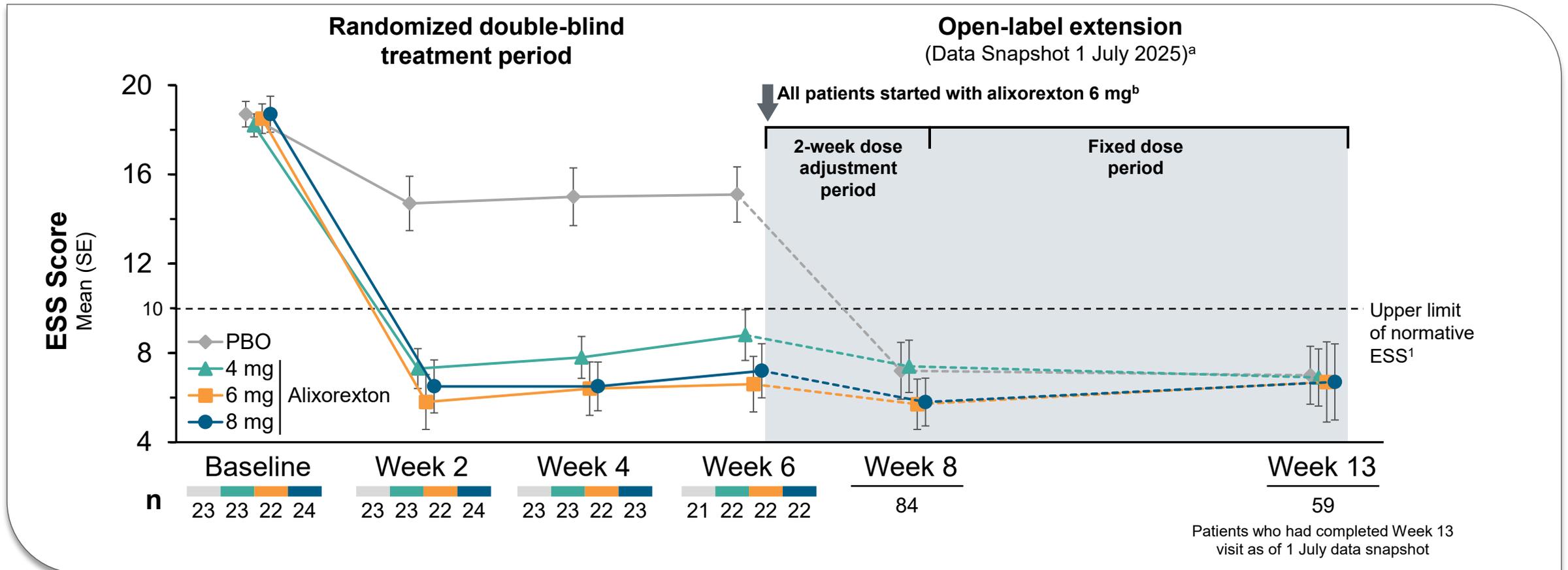
Change from baseline at Week 6 ^a	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
LSM	-3.1	-9.6	-11.8	-11.4
(95% CI of LSM)	(-5.6, -0.7)	(-12.0, -7.1)	(-14.3, -9.3)	(-13.9, -9.0)
LSM difference vs PBO		-6.4	-8.7	-8.3
(95% CI of LSM difference)		(-9.6, -3.3)	(-11.9, -5.5)	(-11.4, -5.2)
P value (Adjusted for multiplicity)		0.01	<0.0001	<0.0001

^aANCOVA model. Missing data were imputed using multiple imputation.

1. Johns MW, Sleep 1991; 14: 540-5.

ANCOVA = analysis of covariance; CI = confidence interval; ESS = Epworth Sleepiness Scale; LSM = least square means; PBO = placebo; SE = standard error.

Alixorexton Improved ESS Scores as Early as Week 2 and Sustained the Effect Through Week 13

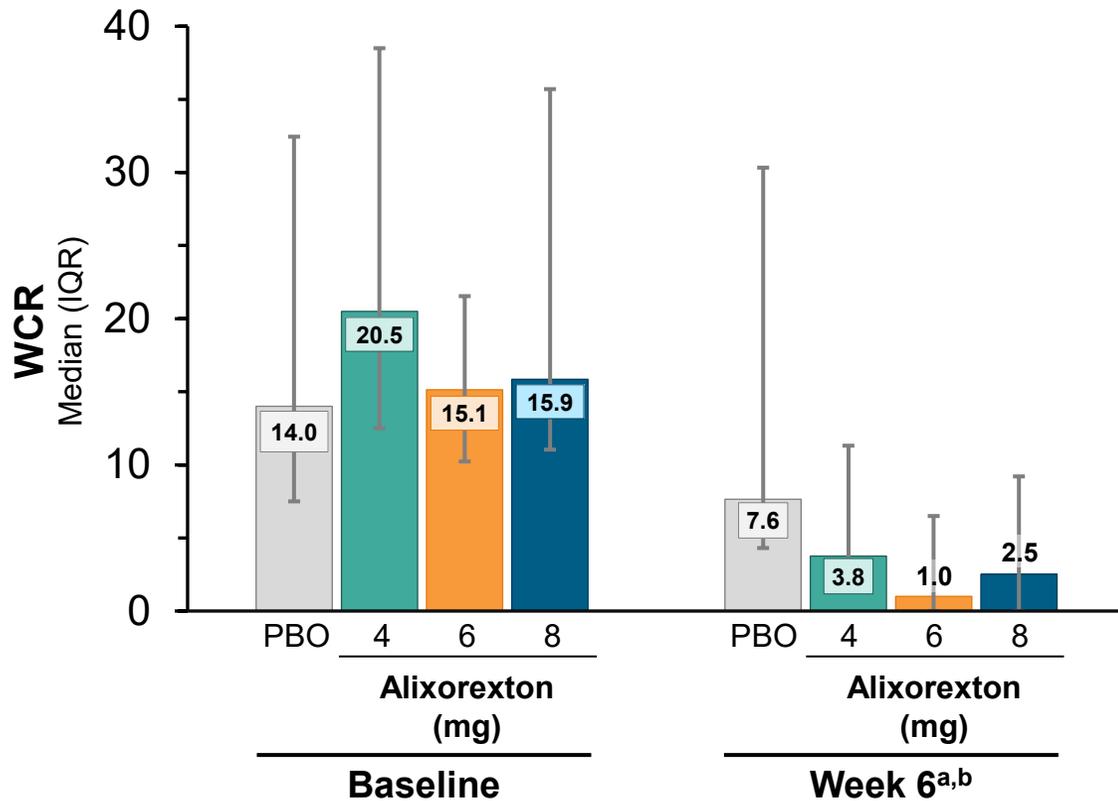


^aThis snapshot of the open-label extension reflects data as of 1 July 2025 from the 59 patients who had completed the Week 13 visit as of that date. Not all patients had completed the open-label extension at the time of this snapshot. ^bDuring the open-label extension (shaded area), all patients were switched to alixorexton 6 mg with dose adjustments during the first 2 weeks at the investigator's discretion.

1. Johns MW, Sleep 1991; 14: 540-5.

ESS = Epworth Sleepiness Scale; PBO = placebo; SE = standard error.

Key Secondary Endpoint: WCR at Week 6 Showed Alixorexton Reduced Cataplexy Events Versus Placebo



Key Secondary Endpoint Analysis

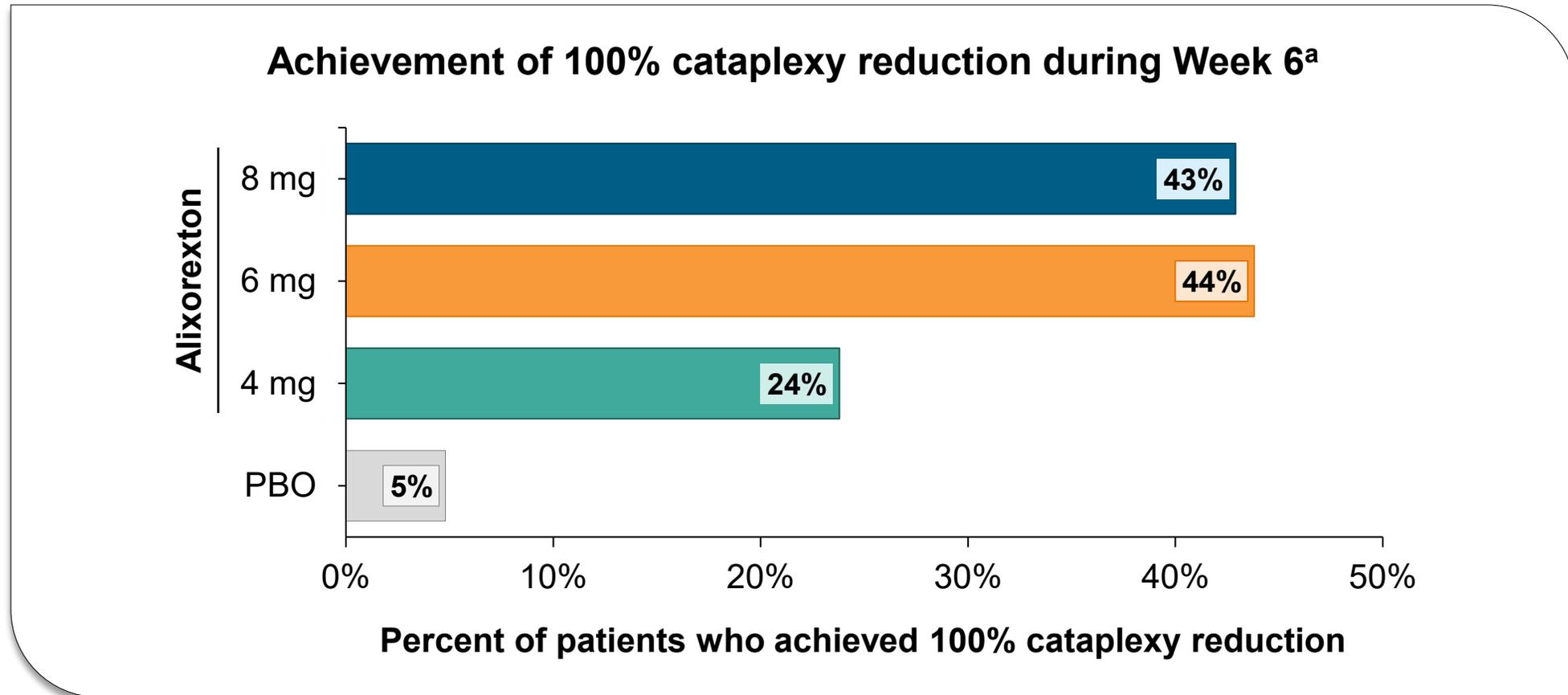
WCR at Week 6 ^{a,c}	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
Mean incidence rate (95% CI of incidence rate)	13.1 (7.5, 22.9)	6.4 (3.6, 11.3)	4.0 (2.2, 7.4)	8.4 (4.7, 15.3)
Rate ratio vs PBO (95% CI of rate ratio)		0.49 (0.23, 1.05)	0.31 (0.14, 0.70)	0.64 (0.30, 1.41)
P value (Adjusted for multiplicity)		0.169	0.01	0.452

^aWeekly cataplexy rate was derived at Week 6 from patients' cataplexy diaries over Weeks 5 and 6. ^bThe minimum number of required cataplexy diaries was 10 days over week 5 and 6.

^cCataplexy events on missing diary days were imputed using multiple imputation. Negative binomial model was used after 100 imputed datasets. Treatment group, baseline weekly cataplexy rate and region were included in the model.

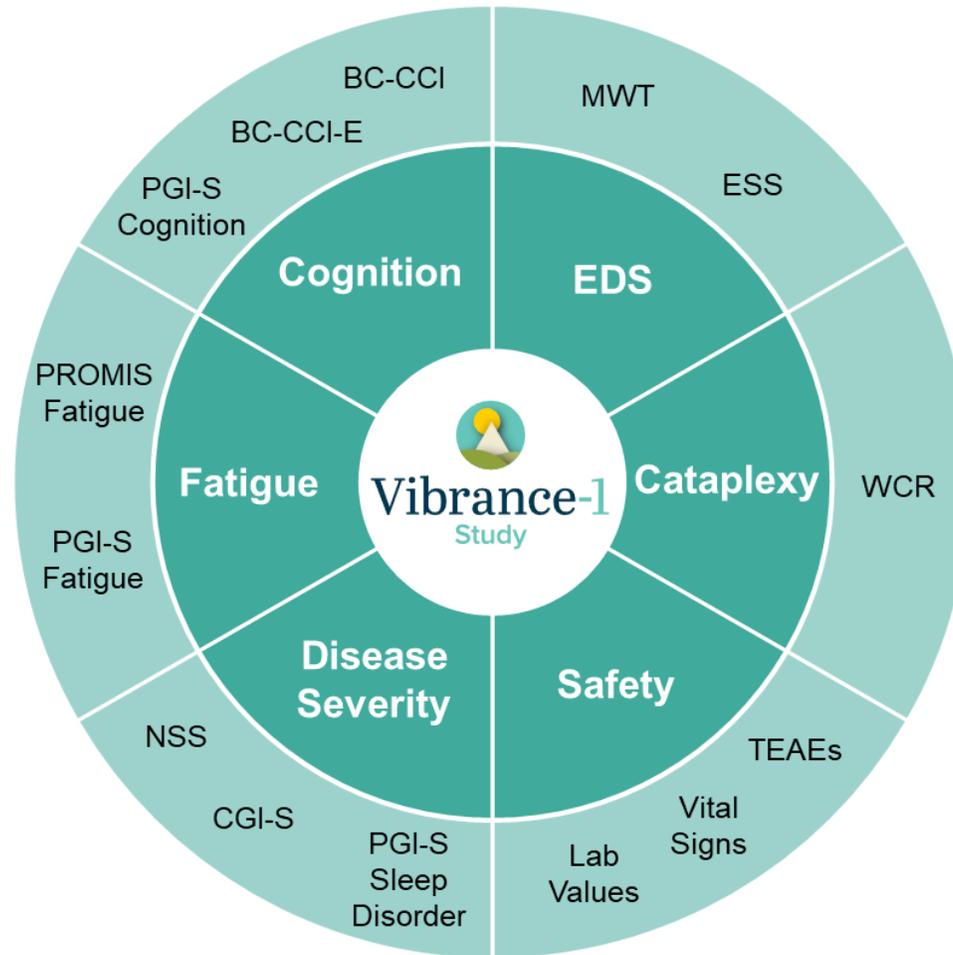
CI = confidence interval; IQR = interquartile range; PBO = placebo; WCR = weekly cataplexy rate.

Many Patients on Alixorexton Experienced No Cataplexy During Week 6



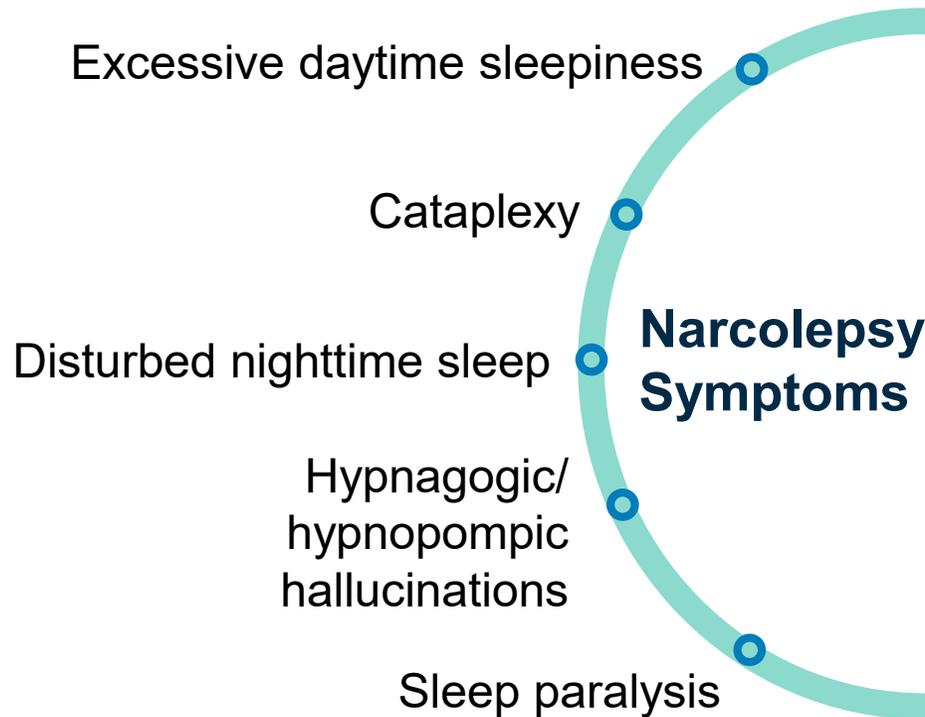
^aThe minimum number of required cataplexy diaries was 5 days weekly.
PBO = placebo.

Vibrance-1 Examined the Effects of Alixorexton on Measures Relevant to the Clinical Needs of Patients With NT1



BC-CCI = British Columbia Cognitive Complaints Inventory; BC-CCI-E = British Columbia Cognitive Complaints Inventory – Expanded; CGI-S = Clinical Global Impression of Severity; ESS = Epworth Sleepiness Scale; MWT = Maintenance of Wakefulness Test; NSS = Narcolepsy Severity Scale; PGI-S = Patient Global Impression of Severity; PROMIS = Patient-Reported Outcomes Measurement Information System; TEAE = treatment-emergent adverse event; WCR = weekly cataplexy rate.

Narcolepsy Severity Scale for Clinical Trials (NSS-CT) Measures the Severity and Impact of the Core Symptoms of Narcolepsy



- 15 items that assess frequency and impact of symptoms on daily life for the past 7 days^{1,2}
- The maximum total score is 57 points; the total score can be categorized into the following levels of severity^{1,2}:

Mild
0-14

Moderate
15-28

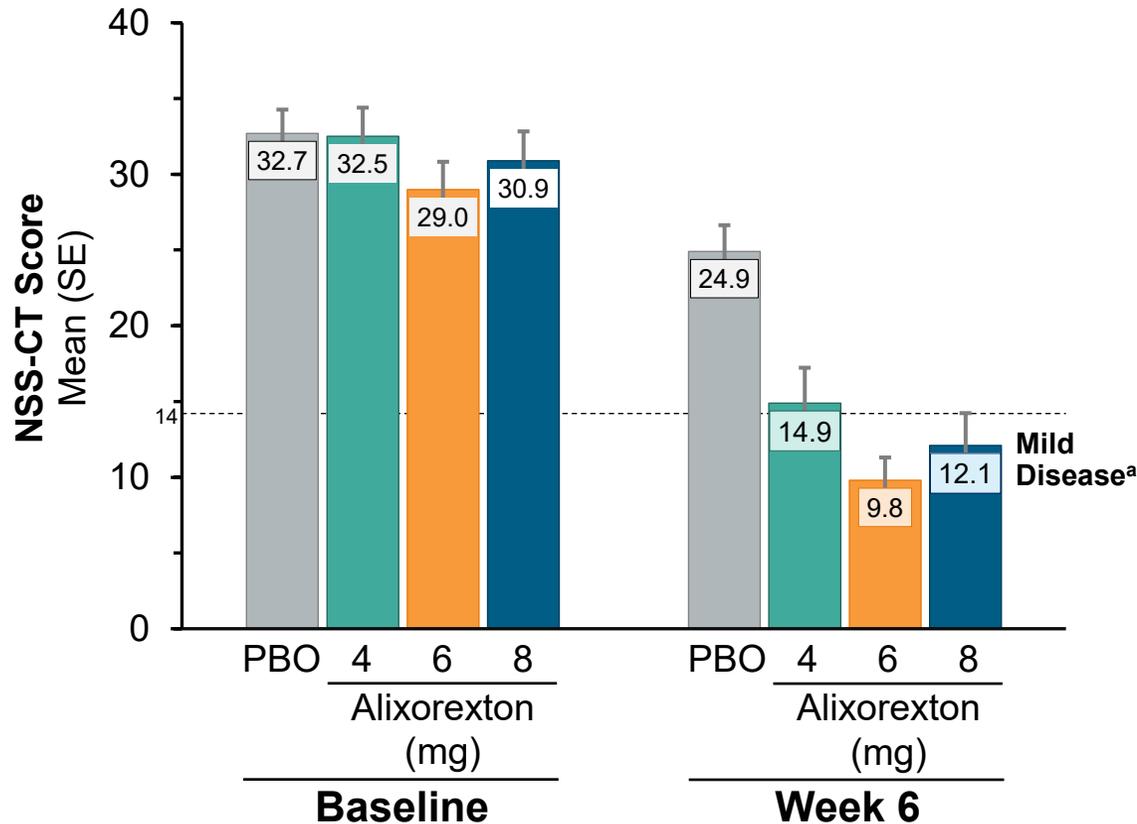
Severe
29-42

Very Severe
43-57

- 8 points is the minimum clinically important difference for evaluating treatment response¹

1. Dauvilliers Y, et al. *Sleep* 2020;43(6):1-11. 2. Dauvilliers Y, et al. *Neurology* 2017;88(14):1358-1365.

Alixorexton Significantly Improved Narcolepsy Symptom Severity in Patients With NT1 from Baseline to Week 6

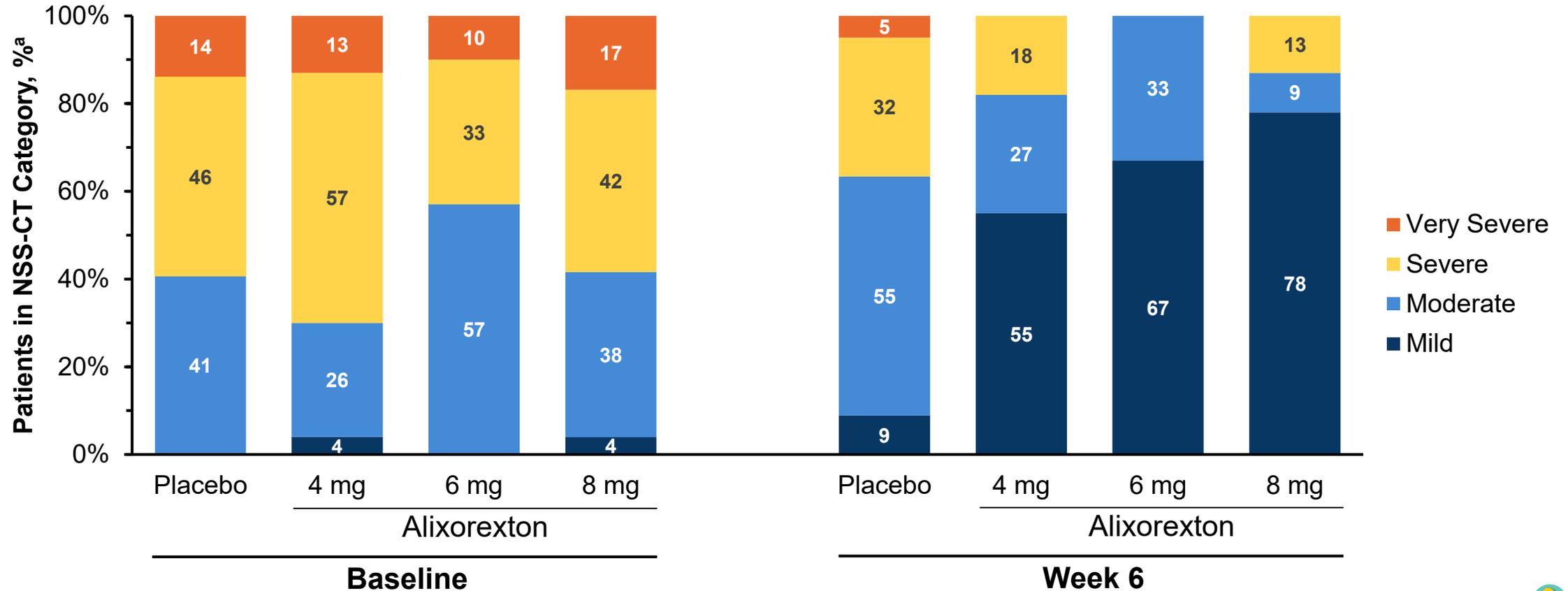


Change from baseline at Week 6 (Exploratory Endpoint)	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
LSM (95% CI of LSM)	-7.1 (-11.1, -3.0)	-16.2 (-20.2, -12.1)	-19.5 (-24.1, -14.8)	-18.1 (-22.1, -14.0)
LSM difference vs PBO (95% CI of LSM difference)		-9.1 (-14.3, -3.9)	-12.4 (-18.0, -6.7)	-11.0 (-16.2, -5.8)
P value (nominal)		0.0008	<0.0001	<0.0001

^aNSS-CT severity ratings: mild, 0-14; moderate, 15-28; severe, 29-42; very severe, 43-57.

CI = confidence interval; LSM = least square means; NSS-CT = Narcolepsy Severity Scale-Clinical Trials; PBO = placebo; SE = standard error.

Most Patients on Alixorexton Reported Mild Narcolepsy Severity at Week 6



^aValues shown within bars are rounded to the nearest whole number and may not sum to 100%.
NSS-CT = Narcolepsy Severity Scale-Clinical Trials.

Fatigue Is a Persistent, Severe, and Debilitating Unmet Need That Impacts the Lives of Patients With Narcolepsy

- Most narcolepsy patients experience fatigue, which often persists even with treatment¹⁻³
- Fatigue negatively affects patients' mental health, functional outcomes and overall quality of life⁴

Commonly Used and Established Patient-reported Measures Specific to Fatigue

PROMIS-Fatigue 6a Short Form

- A 6-item questionnaire scored on a 5-point Likert scale assessing the severity of fatigue in the past 7 days
- Items are scored and transformed to T-scores, ranging from 33.4 to 76.8
- Scores less than 55 are considered normal, while scores ≥ 70 are considered severe

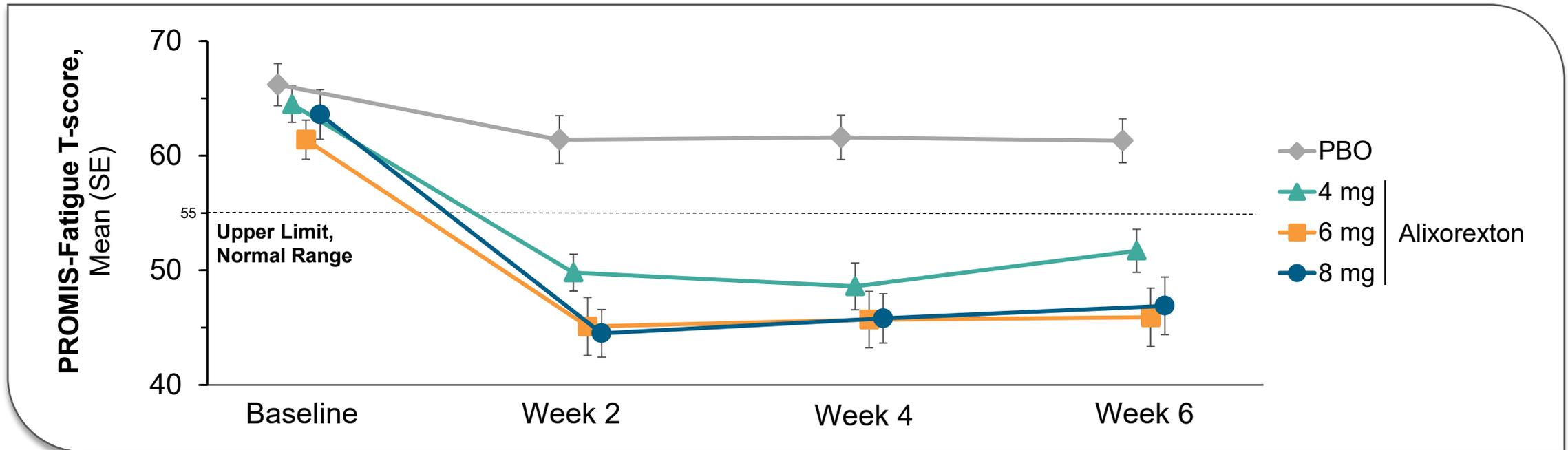
PGI-S Fatigue

- A single item assessing patient-reported severity of fatigue over the past 7 days with scale responses of none, mild, moderate, severe, or very severe

PGI-S = Patient Global Impression of Severity; PROMIS = Patient-Reported Outcomes Measurement Information System.

1. AASM 2023. International Classification of Sleep Disorders – Third Edition: Text Revision, Darien, IL. 2. Maski K, et al. *J Clin Sleep Med* 2017;13(3):419-425. 3. Doane M, et al. Poster presented at Psych Congress 2023. 4. Droogleever F, et al. *Sleep*, 21(2), 163-169.

Alixorexton Significantly Reduced PROMIS-Fatigue Scores from Baseline to Week 6 in Patients With NT1



Change from baseline at Week 6 (Exploratory endpoint)	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
LSM (95% CI of LSM)	-3.3 (-7.5, 0.8)	-12.1 (-16.2, -7.9)	-15.7 (-20.0, -11.4)	-16.2 (-20.4, -12.1)
LSM difference vs PBO (95% CI of LSM difference)		-8.7 (-14.1, -3.3)	-12.4 (-17.9, -6.8)	-12.9 (-18.3, -7.5)
P value (Nominal)		0.0018	<0.0001	<0.0001

CI = confidence interval; LSM = least square means; PBO = placebo; PROMIS = Patient Reported Outcomes Measurement Information System; SE = standard error.

BC-CCI Assesses the Severity and Impact of Cognitive Impairment From the Patient's Perspective

Cognitive Impairment

Perceived Severity

Items include:

- ▶ Forgetfulness/memory problems
- ▶ Poor concentration
- ▶ Trouble expressing thoughts
- ▶ Trouble finding the right word
- ▶ Slow thinking speed
- ▶ Trouble figuring things out or solving problems

Rating Categories

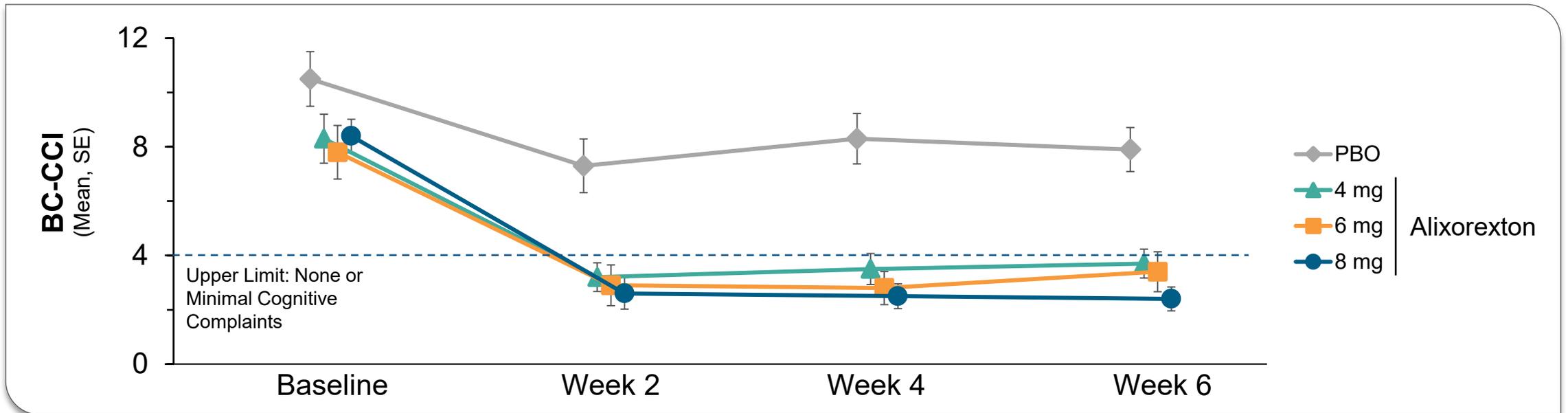
Severe	15 – 18
Moderate	9 – 14
Mild	5 – 8
None or Minimal	0 – 4

Perceived Impact

Expanded version assesses difficulty with:

- ▶ Job
- ▶ Relationships with friends and family
- ▶ Social activities, recreational activities, or hobbies

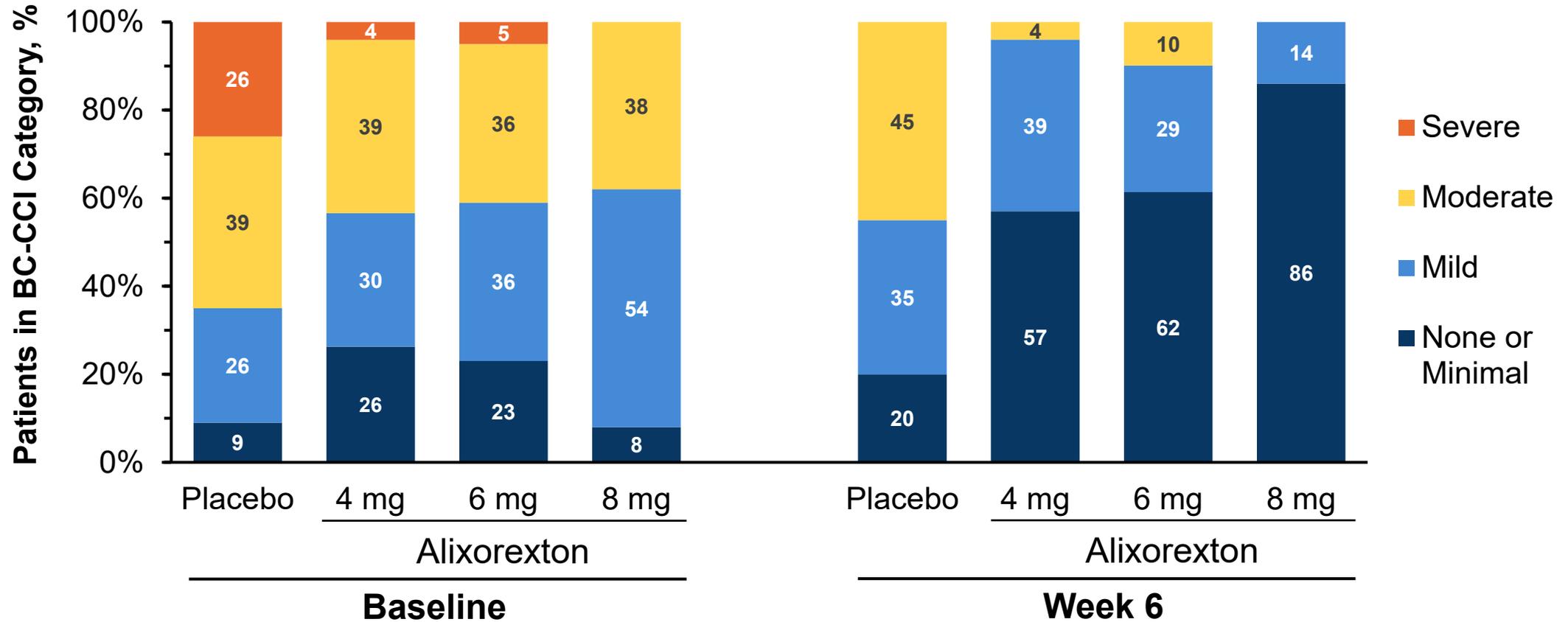
Alixorexton Significantly Reduced Severity of Cognitive Impairment on the BC-CCI From Baseline to Week 6



Change from baseline at Week 6 (Exploratory endpoint)	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
Baseline , mean (SD)	10.5 (4.8)	8.3 (4.3)	7.8 (4.6)	8.4 (3.0)
LSM (95% CI of LSM)	-1.2 (-2.4, 0.0)	-4.7 (-5.9, -3.5)	-4.9 (-6.2, -3.7)	-6.0 (-7.3, -4.8)
LSM difference vs PBO (95% CI of LSM difference)		-3.5 (-5.1, -1.9)	-3.7 (-5.4, -2.1)	-4.8 (-6.4, -3.2)
P value (Nominal)		<0.0001	<0.0001	<0.0001

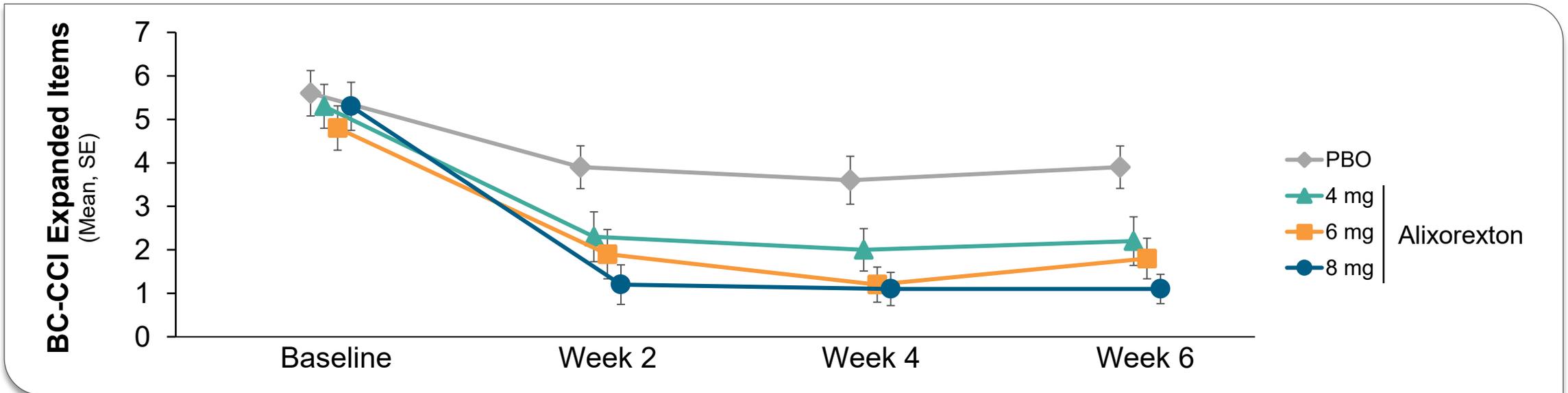
BC-CCI = British Columbia Cognitive Complaints Inventory; CI = confidence interval; LSM = least squares means; PBO = placebo; SD = standard deviation; SE = standard error.

Most Patients on Alixorexton Reported No or Minimal Cognitive Impairment on the BC-CCI at Week 6



^aValues shown within bars are rounded to the nearest whole number and may not sum to 100%.
BC-CCI = British Columbia Cognitive Complaints Inventory.

Alixorexton Significantly Reduced the Impact of Cognitive Impairment on NT1 Patients From Baseline to Week 6



Change from baseline at Week 6 (Exploratory endpoint)	Alixorexton once daily			
	PBO (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
Baseline, mean (SD)	5.6 (2.5)	5.3 (2.4)	4.8 (2.4)	5.3 (2.7)
LSM (95% CI of LSM)	-1.1 (-1.9, -0.2)	-2.8 (-3.6, -1.9)	-3.0 (-3.9, -2.1)	-3.8 (-4.6, -2.9)
LSM difference vs PBO (95% CI of LSM difference)		-1.7 (-2.8, -0.6)	-1.9 (-3.0, -0.8)	-2.7 (-3.8, -1.6)
P value (Nominal)		0.0034	0.001	<0.0001

BC-CCI = British Columbia Cognitive Complaints Inventory; CI = confidence interval; LSM = least squares means; PBO = placebo; SD = standard deviation; SE = standard error.

Patient-reported Outcome Measures Demonstrated Robustness and Consistency Across Doses and Assays



- Narcolepsy Severity Scale (NSS-CT)
- Clinical Global Impression (CGI) – Severity
- Patient Global Impression (PGI) – Severity
- PROMIS-Fatigue 6a Short Form
- PGI-S Fatigue
- British Columbia Cognitive Complaints Inventory (BC-CCI)
- BC-CCI Expanded
- PGI-S Cognition

Alixorexton is the first once-daily orexin 2 receptor agonist to demonstrate normalization of cognitive functioning and fatigue scores on patient-reported scales in addition to clinically meaningful improvements in severity of symptoms in the NT1 population

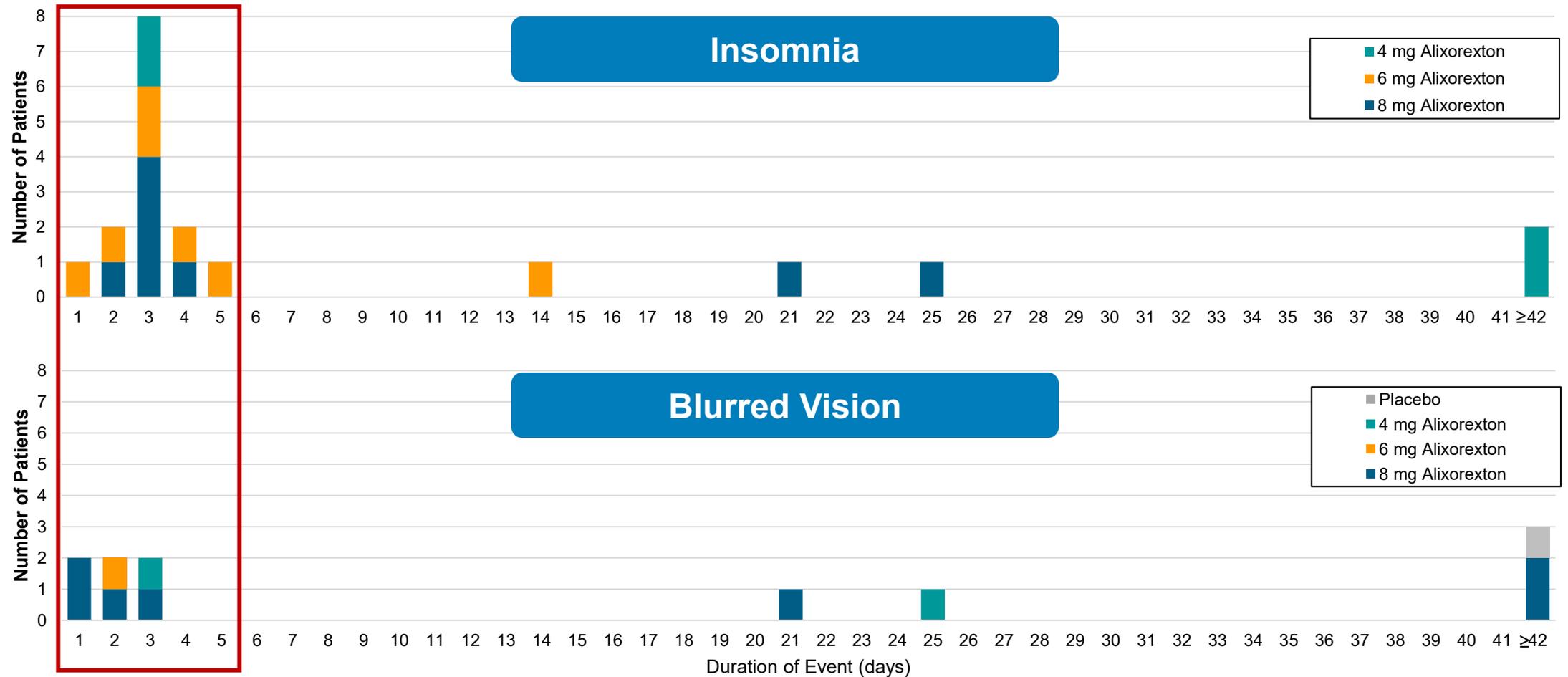
Alixorexton was Generally Well Tolerated Over 6 Weeks of Treatment

n (%)	Alixorexton once daily			
	Placebo (N=23)	4 mg (N=23)	6 mg (N=22)	8 mg (N=24)
Any TEAE^a	11 (48)	20 (87)	20 (91)	21 (88)
Mild	8 (35)	13 (57)	15 (68)	11 (46)
Moderate	3 (13)	6 (26)	5 (23)	8 (33)
Severe	0	1 (4)	0	2 (8)
TEAEs in ≥10% among all alixorexton-treated patients				
Pollakiuria	1 (4)	15 (65)	11 (50)	12 (50)
Insomnia	0	4 (17)	7 (32)	8 (33)
Salivary Hypersecretion	0	5 (22)	5 (23)	7 (29)
Micturition Urgency	1 (4)	2 (9)	4 (18)	4 (17)
Vision Blurred	1 (4)	2 (9)	1 (5)	7 (29)
Drug-related TEAEs^{a,b}	6 (26)	18 (78)	17 (77)	19 (79)
Serious TEAEs	0	0	0	0
TEAEs leading to study drug discontinuation	0	0	0	1 (4)

^aIf a patient had multiple adverse events, the highest severity is presented in summary by severity, and the highest relationship to study drug is presented in summary by relationship.

^bRelationship of TEAE to the drug as determined by the investigator. TEAE = treatment-emergent adverse event.

Majority of Insomnia and Blurred Vision Adverse Events Occurred Early in Treatment and Resolved Within Days



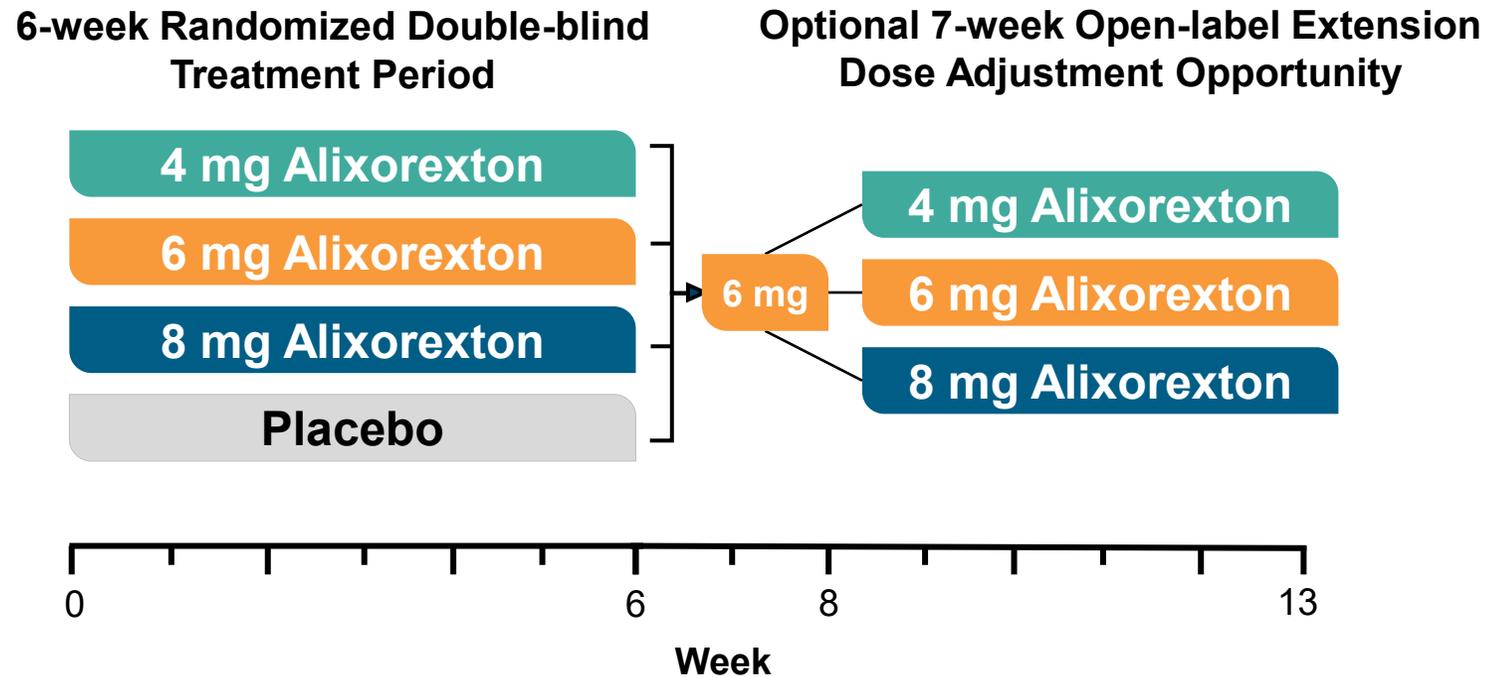
Data from six-week double-blind treatment period. If patient experienced more than 1 event, maximum duration is shown. No events of insomnia reported in placebo group.

Alixorexton was Generally Well Tolerated Over 6 Weeks of Treatment

- Most TEAEs were mild to moderate in severity
- There were no serious TEAEs reported
- Most commonly reported TEAEs occurred within the 1st week of dosing
 - Most insomnia events resolved within 1 week
 - Most urinary events (pollakiuria and micturition urgency) were generally persistent
 - Most vision blurred events were mild, transient or intermittent, and resolved within 3 days
- No clinically meaningful changes in patients treated with alixorexton were noted in heart rate, blood pressure, liver function, or visual exams

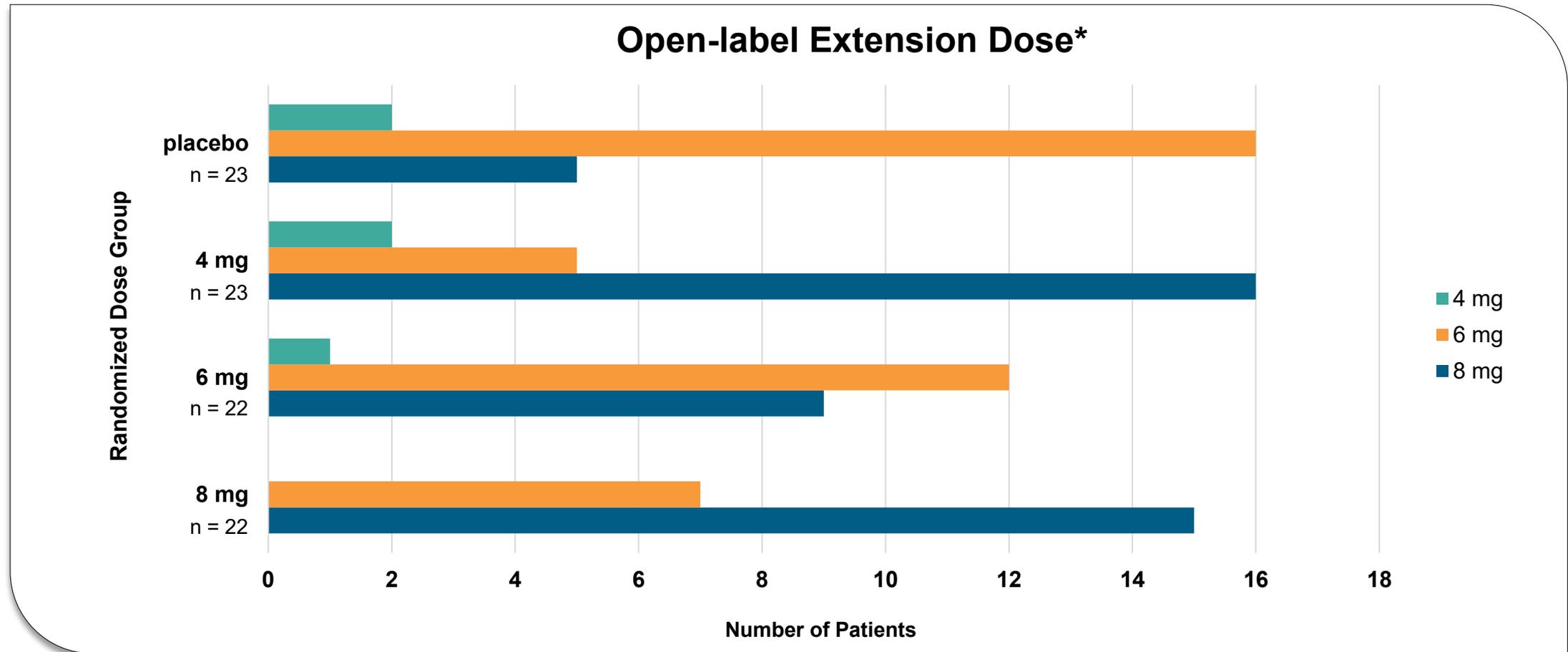
TEAE = treatment-emergent adverse event.

Vibrance-1: Open-label Extension



All patients in the open-label extension period start with 6 mg alixorexton. Dose adjustment possible (up or down) during the first 2 weeks of the optional open-label extension period.

Open-label Extension Dose Adjustment Provided Insight Into Patient Preference



*Ending dose preference. All patients in the open-label extension period start with 6 mg alixorexton. Dose adjustment possible (up or down) during the first 2 weeks of the optional open-label extension period.

Vibrance-1 Open-label Extension: Safety Summary

During the 7-week open-label extension (N=90):

- Alixorexton was generally well tolerated
- Most TEAEs were mild to moderate in severity
- There were no serious TEAEs reported
- For TEAEs most commonly reported in the double-blind period*, in the open-label extension:
 - Onset of events was primarily associated with treatment initiation (patients who received their first exposure to alixorexton in the open-label extension)
 - Onset of new events was low in patients who had prior alixorexton exposure
 - At the 8 mg dose (n=46 in open-label extension), onset of new events was minimal; no new events of pollakiuria, insomnia, salivary hypersecretion or blurred vision were reported

TEAE = treatment-emergent adverse event. *Pollakiuria, insomnia, micturition urgency, salivary hypersecretion or blurred vision

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Conclusions

Once-daily alixorexton:

- ▶ Demonstrated statistically significant, clinically meaningful improvements on the MWT and ESS at Week 6 compared with placebo, achieving a normative wakefulness profile at all doses tested
 - ▷ Improvements on the ESS were observed as early as Week 2 and sustained through Week 13^a
- ▶ Reduced WCR at all doses; achieved statistical significance at the 6 mg dose. Many patients had no cataplexy during Week 6 at all doses tested
- ▶ Was generally well tolerated, with most TEAEs mild to moderate in severity and no serious TEAEs reported
 - ▷ No clinically meaningful changes in heart rate, blood pressure, liver function, or visual exams

Results from Vibrance-1 will inform dose selection for a planned global phase 3 study in patients with NT1

^aBased on data snapshot on 1 July 2025, which included 59 patients who completed the Week 13 visit.

ESS = Epworth Sleepiness Scale; MWT = Maintenance of Wakefulness Test; NT1 = narcolepsy type 1; TEAE = treatment-emergent adverse event; WCR = weekly cataplexy rate.

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