OASIS-1 and –2 responder analysis

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Disclosures

These studies were sponsored by Bayer. **Nick Panay** has lectured and acted in an advisory capacity for: Abbott, Astellas, Bayer, Besins, Gedeon Richter, Mithra, Novo Nordisk, SeCur, Theramex and Viatris. **James Simon** has grant/research support from: AbbVie, Inc., Bayer Healthcare LLC., Daré Bioscience, Ipsen, Mylan/Viatris Inc., Myovant Sciences, ObsEva SA, Sebela Pharmaceuticals Inc., Viveve Medical; has been a consultant/advisory boards of: Bayer HealthCare Pharmaceuticals Inc., Besins Healthcare, California Institute of Integral Studies (CIIS), Camargo Pharmaceutical Services, LLC, Covance Inc., Daré Bioscience, DEKA M.E.L.A S.r.l., Femasys Inc., KaNDy/NeRRe Therapeutics Ltd., Khyria, Madorra Pty Ltd., Mitsubishi Tanabe Pharma Development America, Inc., QUE Oncology Pty, Limited, Scynexis Inc., Sebela Pharmaceuticals, Inc., Sprout Pharmaceuticals, Inc., Vella Bioscience Inc.; has served on the Speaker's bureaus of: Mayne Pharma, Inc., Myovant Sciences, Inc., Pfizer Inc., Pharmavite LLC., Scynexis Inc., TherapeuticsMD; and is a stockholder (direct purchase) in: Sermonix Pharmaceuticals. **Claudio Soares** has received research grants from: Ontario Brain Institute, Clairvoyant Therapeutics, Eisai Inc. and performed consultancy work for: Otsuka, Bayer, Eisai, Diamond Therapeutics. **Rebecca Thurston** has an advisory role for: Astellas, Bayer, Hello Therapeutics. **Cecilia Caetano** and **Lineke Zuurman** are employees of Bayer CC AG. **Nazanin Haseli Mashhadi** is an employee of Bayer PLC. **Susanne Parke, Christian Seitz, Claudia Haberland,** and **Ulrike Krahn** are employees of Bayer AG.

Study overview

Elinzanetant is a dual NK-1,3 receptor antagonist in development for the treatment of moderate-to-severe VMS associated with menopause

OASIS 1 and 2 were pivotal Phase 3 studies assessing the efficacy and safety of elinzanetant over 26 weeks

Participants

Postmenopausal* women aged 40-65 years with ≥50 moderate/severe hot flashes per week

Sites

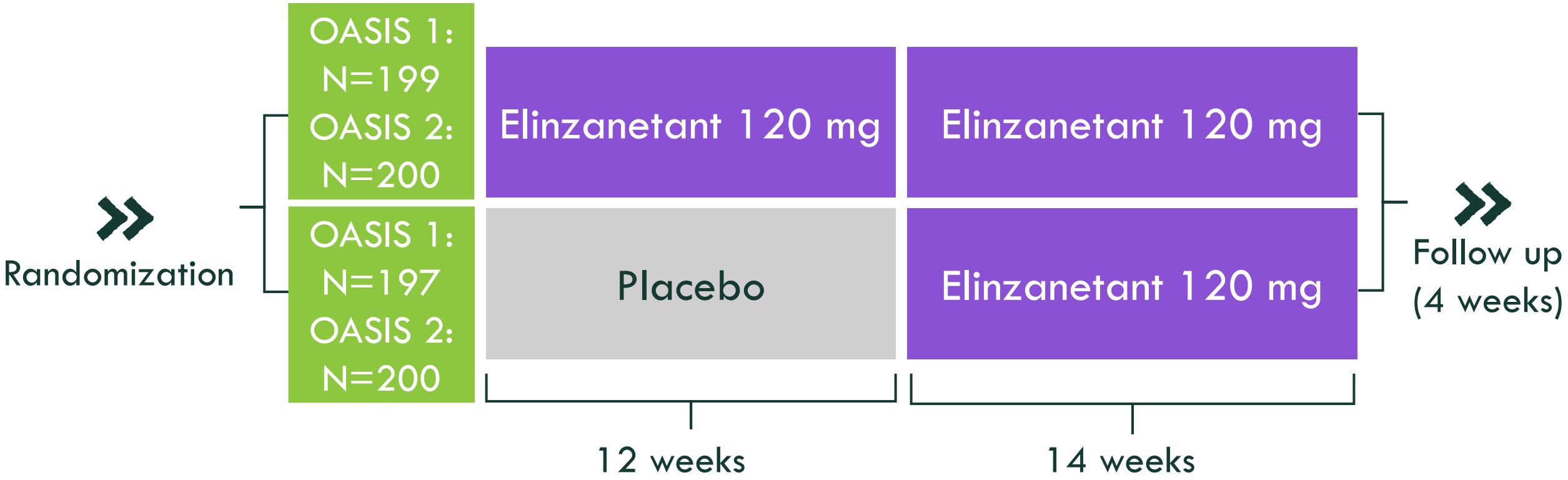
Sites across the US, Canada, Europe and Israel

NK, neurokinin; VMS, vasomotor symptoms.

Pinkerton J, et al. Menopause 2024. Online ahead of print.
doi: 10.1097/GME.0000000000002350

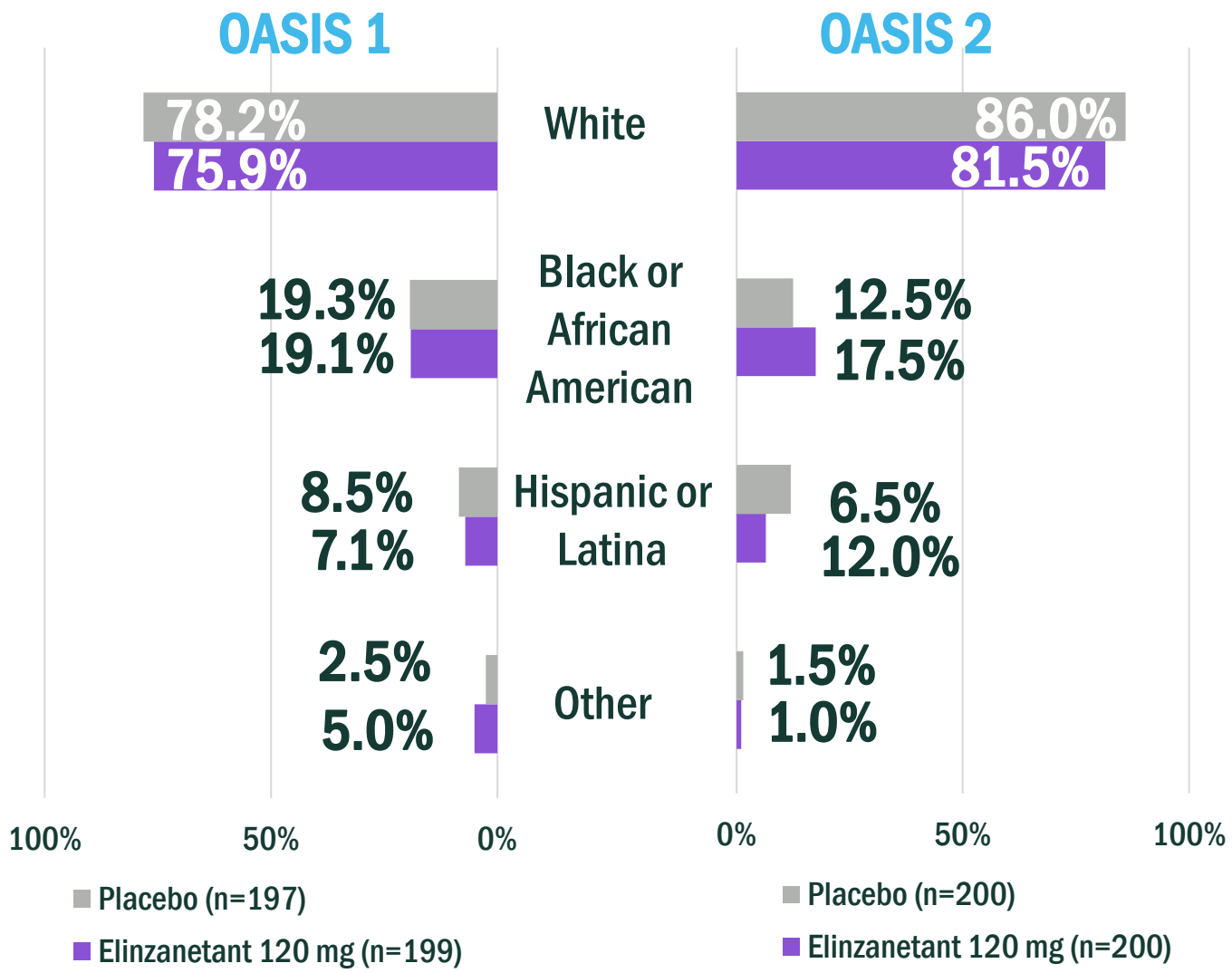
* Naturally or surgically

OASIS-1 and -2: Study design



Participant demographics

Race



Age (years)

OASIS 1

Elinzanetant 120 mg	Placebo
54.6	54.5

OASIS 2

Elinzanetant 120 mg	Placebo
54.8	54.4

BMI (kg/m^2)

OASIS 1

Elinzanetant 120 mg	Placebo
27.8	27.7

OASIS 2

Elinzanetant 120 mg	Placebo
27.8	28.0

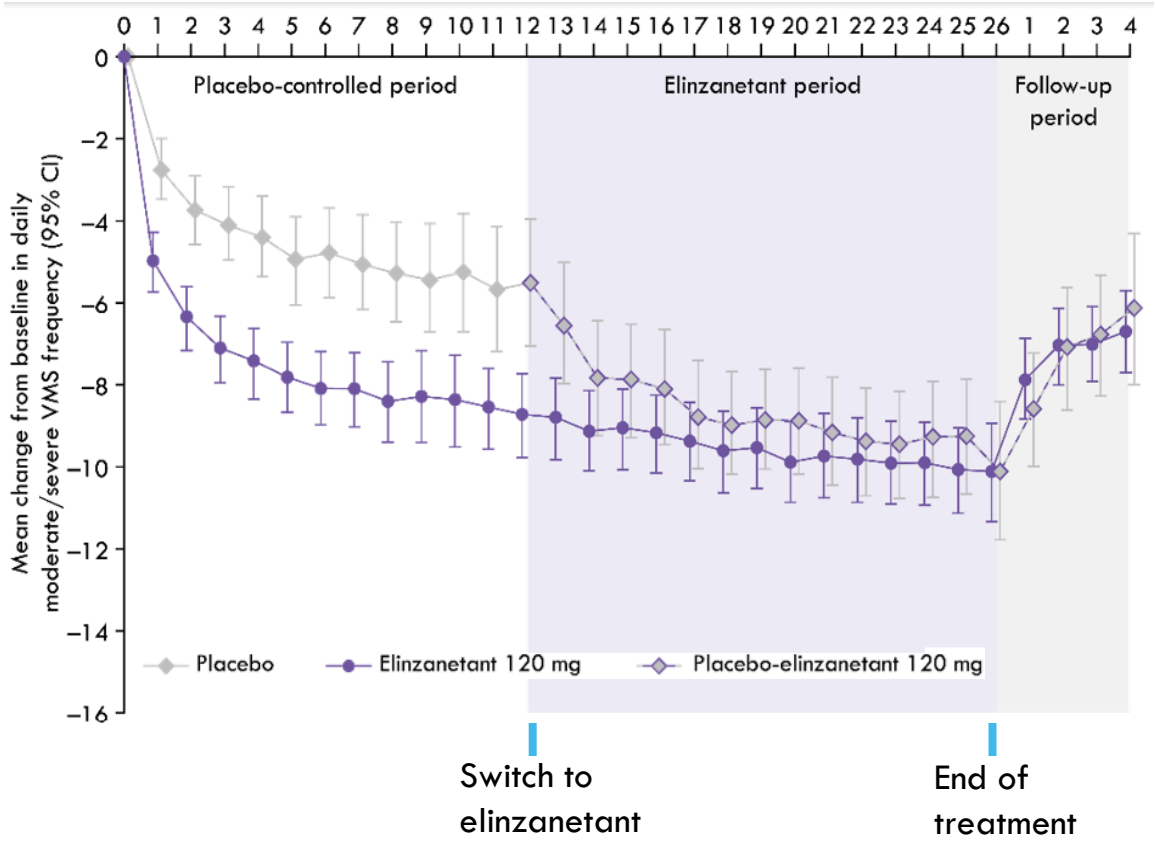
Elinzanetant achieved statistical significance on all tested endpoints in both studies

	Endpoint	OASIS 2 p-value	OASIS 1 p-value	Outcome
Primary	Hot flashes frequency Week 4	<0.0001	<0.0001	✔ Elinzanetant superior
	Hot flashes frequency Week 12	<0.0001	<0.0001	✔ Elinzanetant superior
	Hot flashes severity Week 4	0.0003	<0.0001	✔ Elinzanetant superior
	Hot flashes severity Week 12	<0.0001	<0.0001	✔ Elinzanetant superior
Key secondary	Hot flashes frequency Week 1	0.0013	<0.0001	✔ Elinzanetant superior
	Mean change in PROMIS SD SF 8b total T-score from baseline to week 12	<0.0001	<0.0001	✔ Elinzanetant superior
	Mean change in MENQOL total score from baseline to week 12	0.0059	<0.0001	✔ Elinzanetant superior

Mean change from baseline in frequency of moderate/severe VMS over time

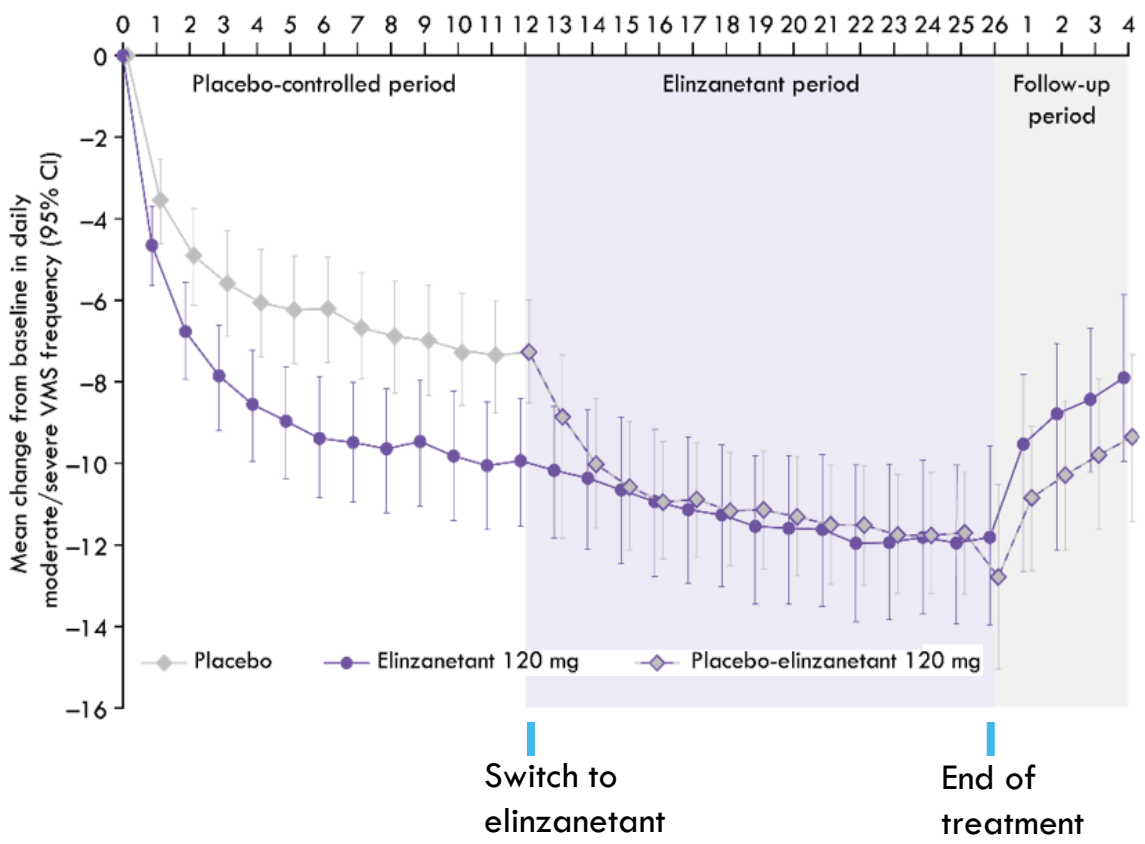
OASIS 1

	Elinzanetant 120 mg	Placebo
n	199	197
Baseline, mean (SD)	13.38 (6.57)	14.26 (13.94)



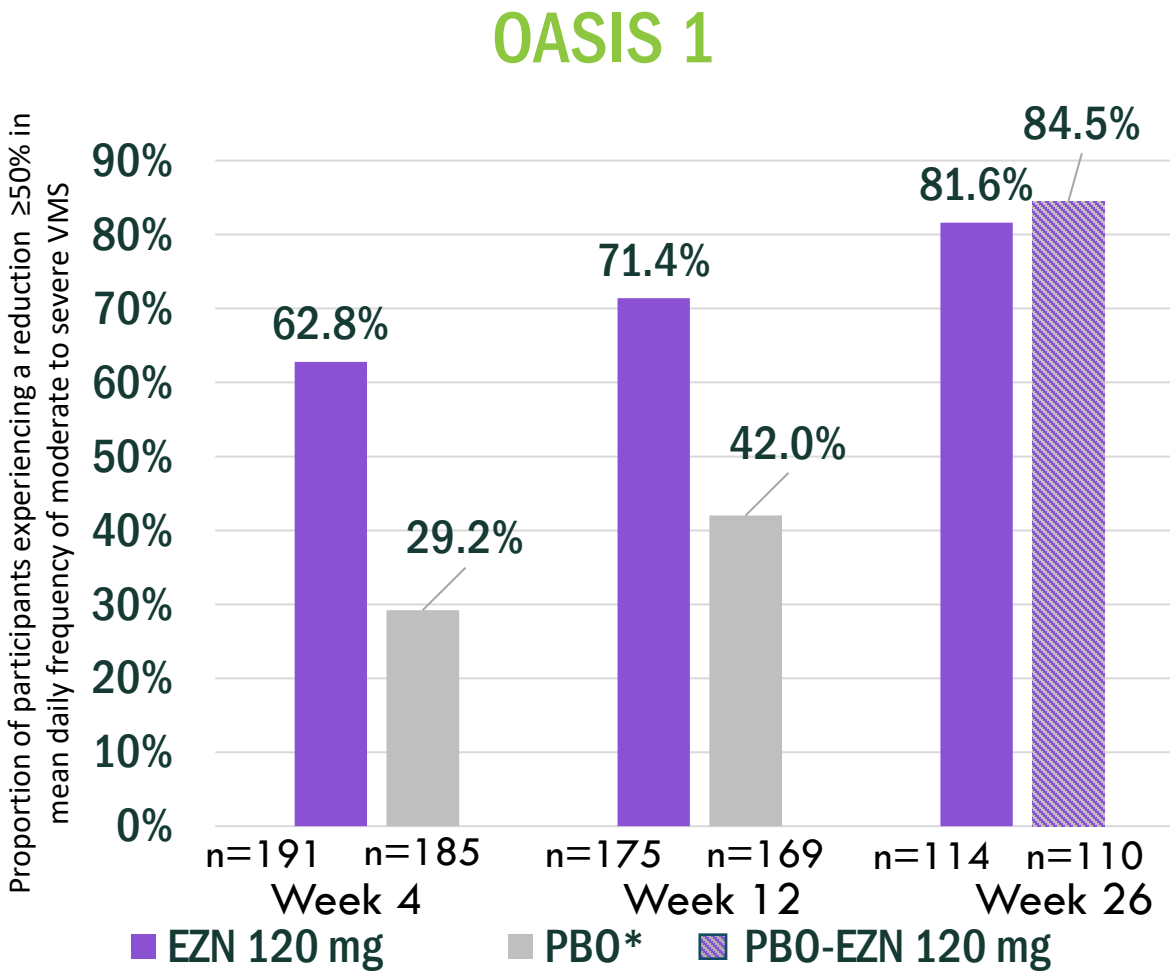
OASIS 2

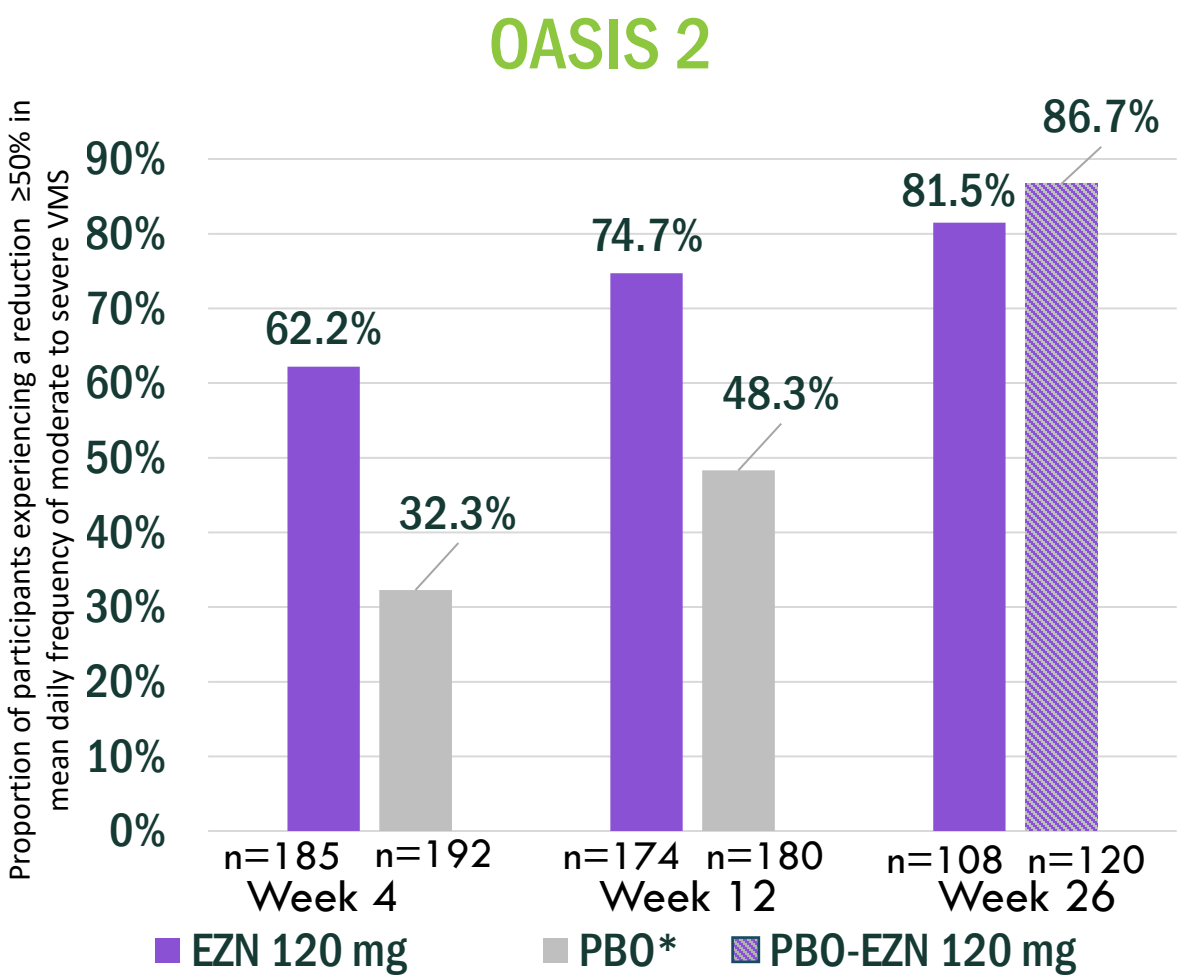
	Elinzanetant 120 mg	Placebo
n	199	200
Baseline, mean (SD)	14.66 (11.08)	16.16 (11.15)



VMS, vasomotor symptoms.

Proportion of participants experiencing a reduction ≥50% in mean daily frequency of moderate to severe VMS at weeks 4, 12, and 26 (treatment response)





*Placebo for weeks 1-12; placebo group switched to elinzanetant from weeks 13-26. EZN, elinzanetant; PBO, placebo; VMS, vasomotor symptoms.

Overview of TEAEs: weeks 1-12

N (%)	OASIS 1		OASIS 2	
	EZN 120 mg week 1-12 (N=199)	PBO week 1-12 (N=194)	EZN 120 mg week 1-12 (N=201)	PBO week 1-12 (N=199)
Any TEAE	102 (51.3%)	94 (48.5%)	89 (44.3%)	76 (38.2%)
Study drug-related TEAE	43 (21.6%)	28 (14.4%)	40 (19.9%)	18 (9.0%)
AE leading to discontinuation of study drug	17 (8.5%)	13 (6.7%)	13 (6.5%)	4 (2.0%)
Any SAE	4 (2.0%)	2 (1.0%)	1 (0.5%)	1 (0.5%)

EZN, elinzanetant; PBO, placebo; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

Most frequent TEAEs: weeks 1-12

N (%)	OASIS 1		OASIS 2	
	EZN 120 mg week 1-12 (N=199)	PBO week 1-12 (N=194)	EZN 120 mg week 1-12 (N=201)	PBO week 1-12 (N=199)
Headache	14 (7.0%)	5 (2.6%)	18 (9.0%)	5 (2.5%)
Fatigue	14 (7.0%)	3 (1.5%)	11 (5.5%)	3 (1.5%)
Arthralgia	10 (5.0%)	10 (5.2%)	5 (2.5%)	2 (1.0%)

EZN, elinzanetant; PBO, placebo; TEAE, treatment-emergent adverse event.

OASIS 1 & 2: Responder summary

- In the OASIS 1 and 2 studies, elinzanetant showed a statistically and clinical meaningful reduction in the frequency of moderate to severe VMS, with quick onset and sustained effect over time.
- In OASIS 1 and 2, 71% and 75% of elinzanetant-treated women experienced a reduction of 50% or more in the frequency of moderate to severe VMS from baseline to week 12, respectively; this percentage further increased to 82% at week 26.
- For women who switched from placebo to elinzanetant, the percentage of responders increased from 42% and 48% at week 12 to 85% and 87% at week 26, in OASIS 1 and 2, respectively.
- The safety profile of elinzanetant was favourable.

Questions?