EFFICACY OF ELINZANETANT ON MENOPAUSE-RELATED VASOMOTOR SYMPTOMS/SLEEP DISTURBANCE IN US AFRICAN AMERICAN WOMEN: POOLED ANALYSIS FROM TWO PHASE 3 TRIALS

Genevieve Neal-Perry[1], Rebecca Dunsmoor-Su[2], Andrew Trigg[3], Sydney Lane[4], Ayman Al-Hendy[5], Pauline M. Maki[6]

[1]University of North Carolina School of Medicine, Chapel Hill, NC, USA; [2]Seattle Clinical Research Center, Seattle, WA, USA; [3]Bayer plc, Reading, UK; [4]Bayer U.S., Whippany, NJ, USA; [5]The University of Illinois College of Medicine, Chicago, IL, USA; [6]The University of Chicago, Chicago, IL, USA

INTRODUCTION

- African American (AA) women report a higher frequency of vasomotor symptoms (VMS), and a higher percentage report sleep difficulty compared with White women[1,2]
- Elinzanetant, a dual neurokinin-1 and -3 receptor antagonist, significantly reduced moderate-to-severe (M/S) VMS frequency and severity, improved sleep disturbance and menopause-related quality of life, and showed a favorable safety profile vs placebo in 2 pivotal Phase III trials (OASIS-1 and OASIS-2)[3]

OBJECTIVE

- In this exploratory post hoc pooled analysis, data from OASIS-1 and OASIS-2 were combined to evaluate the effects of elinzanetant on M/S VMS burden and sleep disturbance in US AA and non-AA women with menopausal M/S VMS

METHODS

Study design and participants

- OASIS-1 (NCT05042362) and OASIS-2 (NCT05099159) were Phase III, randomized, placebo-controlled, multicenter, multicountry, double-blind trials with similar designs
- Naturally or surgically postmenopausal women aged 40–65 years with ≥50 M/S VMS episodes per week were randomized 1:1 to receive either elinzanetant 120 mg for 26 weeks or placebo for 12 weeks followed by elinzanetant for 14 weeks. This post hoc pooled exploratory analysis compares AA and non-AA populations (**Figure 1**)

Endpoints

- Mean change from baseline in frequency of M/S VMS at weeks 1, 4, and 12
- Mean change from baseline in severity of M/S VMS at weeks 4 and 12
- Mean change from baseline to week 12 in Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b (PROMIS SD SF 8b)
- Treatment-emergent adverse events (TEAEs) by treatment group up to week 12 were also reported

- Overall, 133 AA and 277 non-AA women from the United States were randomized. Among AA women, 71 received elinzanetant and 62 received placebo, while among non-AA women, 134 received elinzanetant and 143 received placebo (**Figure 1**)

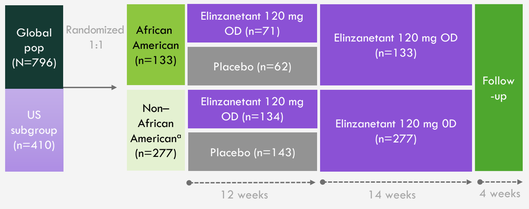

Figure 1. Study design and treatment allocation in the pooled OASIS-1 and OASIS-2 African American vs non–African American women population analysis.
[a]Population consists of White (n=258), Asian (n=4), American Indian or Alaska Native (n=4), or other (excluding African American) (n=11).
OD, once daily; pop, population.

Statistical analyses

- In this post hoc analysis, differences between elinzanetant and placebo are presented as differences in least squares (LS) mean change from baseline with unadjusted 95% confidence intervals (CIs). These endpoints were analyzed using a mixed model with repeated measures (MMRM), and the 1-sided p values were indicative rather than confirmatory

RESULTS

Baseline characteristics

- Baseline characteristics were generally balanced between the elinzanetant and placebo groups (**Table 1**)
- The daily frequency of M/S VMS was higher at baseline for AA women vs non-AA women (**Table 1**)
- The duration of amenorrhea was longer, and the rates of hysterectomy and oophorectomy were higher in AA women vs non-AA women (**Table 1**)

	AA population (n=133)		Non-AA population (n=277)	
Characteristic	Elinzanetant 120 mg (n=71)	Placebo (n=62)	Elinzanetant 120 mg (n=134)	Placebo (n=143)
Age, y, mean (SD)	55.9 (5.2)	54.8 (5.5)	54.5 (5.1)	54.9 (4.3)
Race, n (%)				
White	0	0	122 (91.0)	136 (95.1)
Black or African American	71 (100.0)	62 (100.0)	0	0
Asian	0	0	2 (1.5)	2 (1.4)
American Indian or Alaska Native	0	0	2 (1.5)	2 (1.4)
Multiple	0	0	3 (2.2)	0
Not reported	0	0	5 (3.7)	3 (2.1)
BMI, kg/m², mean (SD)	30.4 (4.6)	30.6 (4.4)	27.9 (5.1)	28.7 (4.6)
Smoking history, never, n (%)	46 (64.8)	39 (62.9)	96 (71.6)	92 (64.3)
Number of pregnancies, mean (SD)	2.8 (1.5)	2.9 (2.1)	2.7 (1.7)	2.7 (1.8)
Number of births, mean (SD)	2.1 (1.2)	2.0 (1.8)	2.1 (1.4)	1.9 (1.2)
Duration of amenorrhea, y, mean (SD)	10.8 (6.8)	9.7 (7.2)	7.6 (6.9)	7.9 (6.6)
Hysterectomy, yes, n (%)	43 (60.6)	43 (69.4)	54 (40.3)	56 (39.2)
Oophorectomy, yes, n (%)	18 (25.4)	23 (37.1)	28 (20.9)	28 (19.6)
Baseline M/S VMS daily frequency, mean (SD)	16.7 (16.3)	18.9 (23.1)	13.5 (6.1)	15.0 (11.3)
Baseline VMS daily severity, mean (SD)	2.6 (0.2)	2.6 (0.2)	2.6 (0.2)	2.5 (0.2)

Table 1. Baseline characteristics of AA women vs non-AA women in the United States.
AA, African American; BMI, body mass index; M/S, moderate-to-severe; SD, standard deviation; VMS, vasomotor symptoms.

Daily frequency of VMS

- In the MMRM analysis, reductions from baseline in daily frequency of M/S VMS among AA women (LS mean change [95% CI]) were greater with elinzanetant than with placebo at week 1 (-2.95 [-5.34, -0.55]; p=0.0079), week 4 (-3.63 [-7.18, -0.08]; p=0.0226), and week 12 (-3.90 [-8.35, 0.55]; p=0.0428)[a] (**Figure 2A**)
- Reductions from baseline in daily frequency of M/S VMS among non-AA women (LS mean change [95% CI]) were greater with elinzanetant than with placebo at week 1 (-1.88 [-3.04, -0.71]; p=0.0008), week 4 (-3.49 [-4.95, -2.02]; p<0.0001), and week 12 (-3.47 [-5.02, -1.92]; p<0.0001)[a] (**Figure 2B**)

[a]1-sided p values were indicative rather than confirmatory.

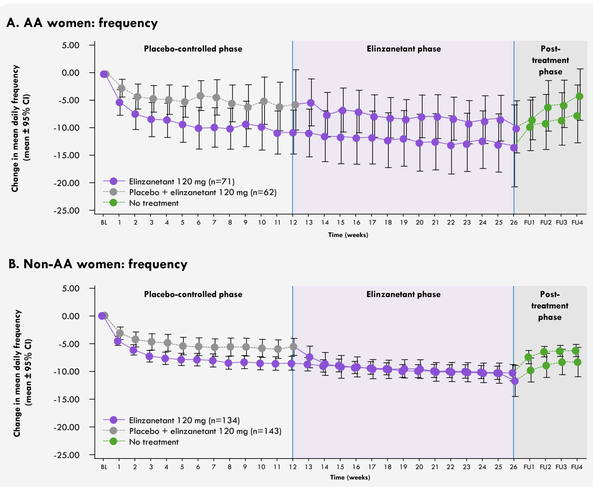

Figure 2. Mean change from baseline in average daily frequency in AA women (A) and non-AA women (B) of M/S VMS over time.
AA, African American; BL, baseline; CI, confidence interval; FU, follow-up; M/S, moderate-to-severe; VMS, vasomotor symptoms.

Daily severity of VMS

- In the MMRM analysis, reductions from baseline in daily severity of M/S VMS among AA women (LS mean change [95% CI]) were greater with elinzanetant than with placebo at week 12 (-0.21 [-0.44, 0.02]; p=0.0374) but not week 4 (-0.07 [-0.25, 0.10]; p=0.2042)[a] (**Figure 3A**)
- Reductions from baseline in daily severity of M/S VMS among non-AA women (LS mean change [95% CI]) were greater with elinzanetant than with placebo at week 4 (-0.33 [-0.46, -0.20]; p<0.0001) and week 12 (-0.40 [-0.58, -0.23]; p<0.0001)[a] (**Figure 3B**)

[a]1-sided p values were indicative rather than confirmatory.

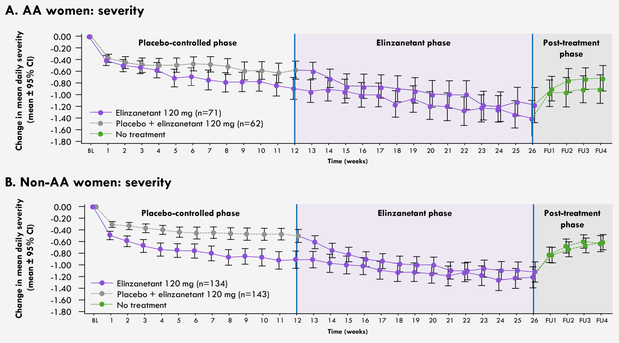

Figure 3. Mean change from baseline in average daily severity in AA women (A) and non-AA women (B) of M/S VMS over time.
AA, African American; BL, baseline; CI, confidence interval; FU, follow-up; M/S, moderate-to-severe; VMS, vasomotor symptoms.

Sleep disturbance

- Reductions from baseline to week 12 in PROMIS SD SF 8b (difference in LS means [95% CI]) were greater with elinzanetant vs placebo in AA women (-5.13 [-8.13, -2.14]; p=0.0004) and in non-AA women (-3.84 [-5.60, -2.09]; p<0.0001) (**Figure 4A, 4B**)
- In those AA and non-AA women who switched to elinzanetant from placebo after week 12, further numerical improvements were observed for PROMIS SD SF 8b to week 26 (**Figure 4A, 4B**)

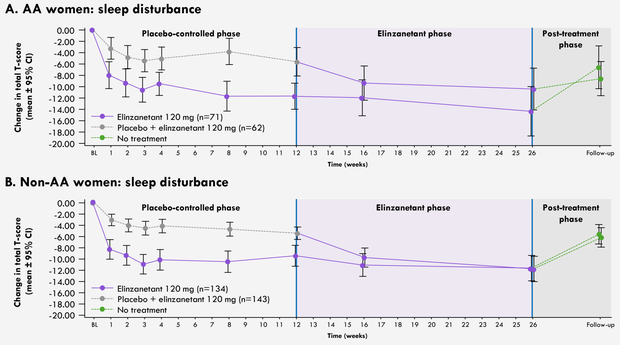

Figure 4. Mean change from baseline in PROMIS SD SF 8b total T-score in AA women (A) and non-AA women (B).
AA, African American; BL, baseline; CI, confidence interval; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b.

Safety

- TEAEs up to week 12 were reported in 25 (35.2%) vs 22 (36.7%) AA women and 67 (50.0%) vs 59 (41.5%) non-AA women receiving elinzanetant vs placebo, respectively (**Table 2**)
- In AA women, the most commonly reported AEs[a] during the 12-week placebo-controlled treatment period were somnolence (5.6% vs 0%), headache (4.2% vs 1.7%), and fatigue (4.2% vs 1.7%) in the elinzanetant and placebo groups, respectively (**Table 2**)
- No cases of liver enzyme elevations meeting criteria for liver injury were reported in either AA or non-AA women

	AA population (n=131)		Non-AA population (n=276)	
	Elinzanetant 120 mg (n=71)	Placebo (n=60)	Elinzanetant 120 mg (n=134)	Placebo (n=142)
Any TEAE, n (%)	25 (35.2)	22 (36.7)	67 (50.0)	59 (41.5)
Most commonly reported TEAEs, n (%)[a]				
Headache	3 (4.2)	1 (1.7)	9 (6.7)	5 (3.5)
Increase in depression rating scale score	3 (4.2)	2 (3.3)	7 (5.2)	6 (4.2)
Arthralgia	1 (1.4)	2 (3.3)	10 (7.5)	6 (4.2)
Fatigue	3 (4.2)	1 (1.7)	7 (5.2)	2 (1.4)
Somnolence	4 (5.6)	0	1 (0.7)	0

Table 2. TEAEs up to week 12.
N values are provided for the safety analysis set, which is a subset of all randomized participants.
[a]Most commonly reported TEAEs in >5% of patients in any treatment group. AA, African American; TEAE, treatment-emergent adverse event.

KEY TAKEAWAYS

This pooled analysis of OASIS-1 and OASIS-2 highlights the importance of understanding treatment effects in women across different racial backgrounds

Elinzanetant reduced M/S VMS frequency in both AA and non-AA women, with improvements comparable between groups despite higher baseline symptom burden in AA women

Elinzanetant improved sleep disturbance at week 12 compared with placebo in both AA and non-AA women

Elinzanetant was also well tolerated in the AA population, with no cases of liver enzyme elevations meeting criteria for liver injury reported in either AA or non-AA women

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DISCLOSURES

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