# POSTER 070

# Effect of elinzanetant for the treatment of vasomotor symptoms associated with menopause across race and ethnicity subgroups: pooled data from two Phase 3 studies

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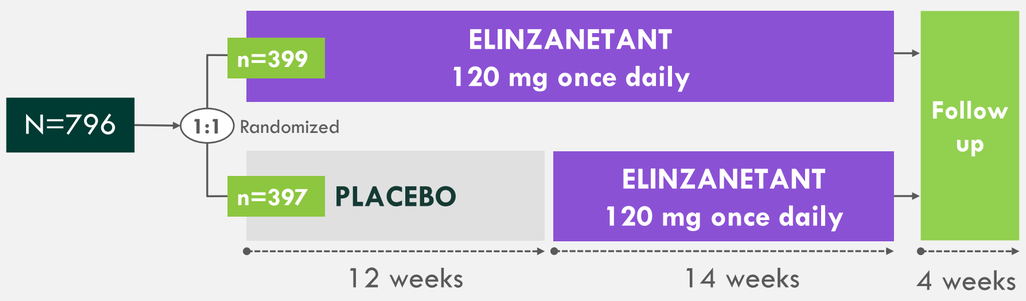
## INTRODUCTION

In the pivotal randomized Phase 3 trials, OASIS 1 and 2, elinzanetant (EZN), a dual neurokinin-1 and -3 receptor antagonist, significantly reduced the frequency and severity of menopausal vasomotor symptoms (VMS; also known as hot flashes) compared with placebo (PBO).[1] It is important to understand the efficacy of EZN across race and ethnicity. Therefore, this analysis aimed to evaluate the efficacy of EZN in pre-specified race and ethnicity subgroups using pooled data from the OASIS 1 and 2 trials.

## METHODS

### Participants and interventions

Naturally/surgically postmenopausal women aged 40–65 years with ≥50 moderate-to-severe VMS episodes/week were randomized 1:1 to receive EZN 120 mg for 26 weeks or PBO for 12 weeks followed by EZN for 14 weeks.




### Main outcome measures

Participants were evaluated by:

**Race:**

- Black/African American
- White

**Ethnicity:**

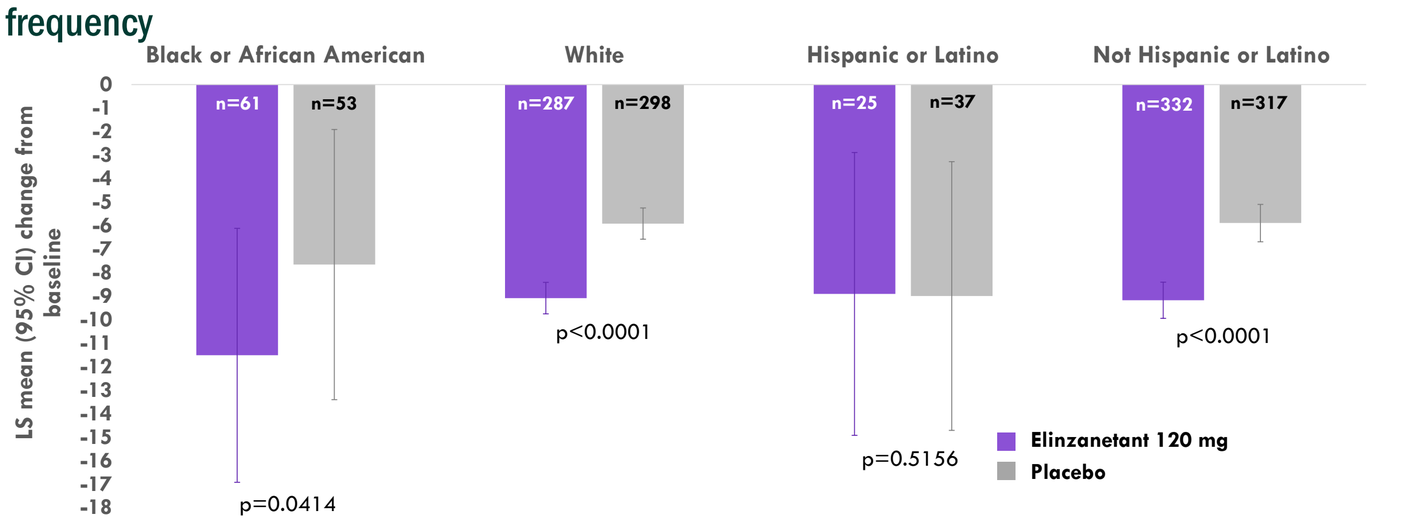
- Hispanic/Latino
- Not Hispanic/Latino

Data were pooled from OASIS 1 and 2 trials. Other subgroups were not included in the analysis due to small sample size. Mean changes in daily moderate-to-severe VMS frequency from baseline to week 12 as well as the interaction between subgroup and treatment were analyzed by a mixed model with repeated measures. All p-values were nominal and one-sided (α level of 0.025).

## RESULTS

- At **baseline,** there was some **variation** in mean daily VMS frequency across Black/African American, White, Hispanic/Latino and Not Hispanic/Latino subgroups (**Table 2**).
- Mean (SD) reductions from baseline to week 12 in daily VMS frequency were numerically **greater with EZN** than with PBO across **Black/African American, White,** and **non-Hispanic/Latino** subgroups (**Figure 1**); differences were nominally significant for White and non-Hispanic/Latino subgroups.
- In the **Hispanic/Latino subgroup,** larger mean reductions in VMS frequency from baseline to week 12 were seen in the PBO group, which were **numerically greater than with EZN,** but differences did not reach statistical significance (**Figure 1**).
- The differences in least square (LS) means between EZN and PBO were not nominally significantly different between White and Black/African American subgroups or between Hispanic/Latino and non-Hispanic/Latino subgroups.

### Figure 1. LS mean change from baseline to week 12 in average daily moderate-to-severe VMS frequency




n = number of subjects with observed value for this timepoint.

### Table 1. Participant race and ethnicity[a]

| | EZN 120 mg (n=399) | PBO (n=397) |
|---|---|---|
| **Race, n (%)** | | |
| White | 314 (78.7%) | 326 (82.1%) |
| Black or African American | 73 (18.3%) | 63 (15.9%) |
| **Ethnicity, n (%)** | | |
| Not Hispanic or Latino | 366 (91.7%) | 354 (89.2%) |
| Hispanic or Latino | 30 (7.5%) | 38 (9.6%) |

[a]Some subgroups not included in this analysis due to small sample size.

### Table 2. Average daily moderate-to-severe VMS frequency by race and ethnicity

| | Black or African American | | White | | Hispanic or Latino | | Not Hispanic or Latino | |
|---|---|---|---|---|---|---|---|---|
| | EZN 120 mg (n=73) | PBO (n=63) | EZN 120 mg (n=314) | PBO (n=326) | EZN 120 mg (n=30) | PBO (n=38) | EZN 120 mg (n=366) | PBO (n=354) |
| Baseline, mean (SD) | 16.6 (16.1) | 19.1 (23.0) | 13.4 (6.5) | 14.6 (9.4) | 15.5 (8.5) | 22.6 (17.7) | 13.9 (9.2) | 14.4 (11.7) |
| LS mean change from baseline to week 12 (SE) | -11.5 (2.8) | -7.7 (2.9) | -9.1 (0.3) | -5.9 (0.3) | -8.9 (3.1) | -9.0 (2.9) | -9.2 (0.4) | -5.9 (0.4) |
| Difference in LS means (SE) [95% CI] | -3.9 (2.2) [-8.2, 0.5] | | -3.2 (0.5) [-4.1, -2.2] | | 0.1 (2.4) [-4.5, 4.7] | | -3.3 (0.6) [-4.4, -2.2] | |
| p-value (one-sided) | p=0.0414 | | p<0.0001 | | p=0.5156 | | p<0.0001 | |

## CONCLUSIONS

**EZN was consistently efficacious in reducing moderate-to-severe VMS frequency across Black/African American, White, and non-Hispanic/Latino postmenopausal women**

VMS can vary across race and ethnicity; therefore, it is important to understand the efficacy of VMS treatments across these groups

Reductions in VMS frequency with EZN were nominally significantly greater than with PBO for White and non-Hispanic/Latino subgroups

A larger PBO response was observed in the Hispanic/Latino subgroup; small group numbers and large relative baseline differences in VMS frequency may limit the generalizability of these findings

## ACKNOWLEDGEMENTS

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## REFERENCES

1. Pinkerton JV, et al. JAMA 2024. doi:10.1001/jama.2024.14618.

## DISCLOSURES

JoAnn Pinkerton was principal investigator on the OASIS 2 clinical trial, fees to the University of Virginia and has been a consultant with Bayer HealthCare Pharmaceuticals and Pfizer. James Simon was principal investigator on the OASIS 1 trial; 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. Hadine Joffe has received grants from: NIH, Merck, Pfizer and has performed consultancy work for: Bayer, Merck, Hello Therapeutics. Pauline Maki has performed consultancy work for: Abbott, Astellas, Bayer HealthCare AG, and Pfizer and received speaking honorarium from: Mithra, equity in Alloy, MidiHealth, and Estrigenix. Rossella E. Nappi had past financial relationships (lecturer, member of advisory boards and/or consultant) with Boehringer Ingelheim, Ely Lilly, Endoceutics, Palatin Technologies, Pfizer Inc., Procter & Gamble Co, TEVA Women's Health Inc., and Zambon SpA. At present, she has on-going relationship with Abbott, Astellas, Bayer HealthCare AG, Besins Healthcare, Exeltis, Fidia, Gedeon Richter, HRA Pharma, Merck & Co, Novo Nordisk, Organon & Co, Shionogi Limited, Theramex, Viatris, and Vichy Laboratories. Nick Panay has lectured and acted in an advisory capacity for: Abbott, Astellas, Bayer, Besins, Gedeon Richter, Mithra, Novo Nordisk, SeCur, Theramex, and Viatris. 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 acted in an advisory capacity for Bayer, Astellas, and Hello Therapeutics. Cecilia Caetano and Lineke Zuurman are employees of Bayer CC AG. Claudia Haberland is an employee of Bayer AG. Chenshuang Lu is an employee of Bayer U.S. LLC.