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Proportion of participants achieving at least 50%, 75%, or 100% reductions in VMS frequency with elinzanetant in a pooled analysis of OASIS-1 and -2

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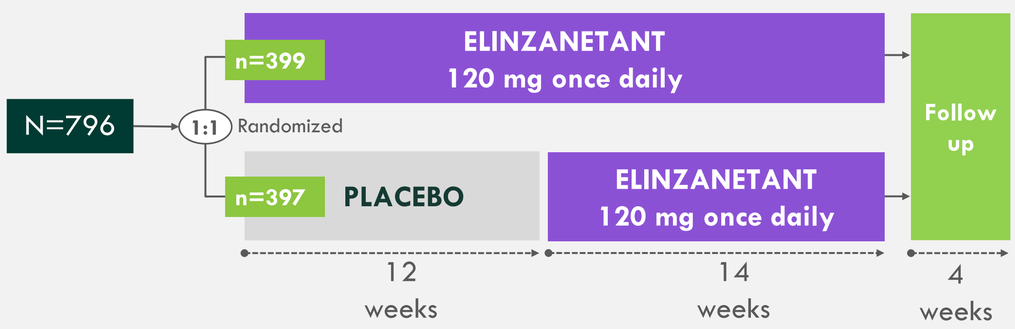
INTRODUCTION

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] This analysis aimed to further characterize the efficacy of EZN based on the proportion of participants achieving different levels of response to the treatment in relation to VMS frequency.

METHODS

Participants and interventions

Overall, 796 naturally/surgically postmenopausal women aged 40–65 years experiencing ≥50 moderate-to-severe VMS/week were randomized 1:1 to receive EZN 120 mg for 26 weeks or PBO for 12 weeks followed by EZN for 14 weeks.



Post-hoc responder analysis

- Post-hoc treatment responder analyses were carried out on pooled OASIS-1 and -2 clinical trial data.
- All participants in the full analysis set who provided data at each time point of interest were included.
- Analyses assessed the proportion of participants who experienced a reduction in frequency of moderate-to-severe VMS of:

  ≥50%, ≥75%, or 100%

  from baseline to weeks 4, 12, and 26, as reported by participants using Hot Flash Daily Diaries (HFDD).
- Within-patient changes were assessed for each patient in comparison with their own baseline, presented by treatment arm.

RESULTS

- By week 4 (**Figure 1**) in the EZN group (n=376), 62.5% of participants achieved a ≥50% reduction, 36.4% a ≥75% reduction, and 6.6% a 100% reduction in moderate-to-severe VMS frequency from baseline. In the PBO group (n=377), 30.8%, 15.1%, and 2.7% achieved a ≥50%, ≥75%, and 100% reduction, respectively.
- By week 12 (**Figure 2**) in the EZN group (n=349), 73.1%, 50.7%, and 13.8% of participants achieved a ≥50%, ≥75%, and 100% reduction, respectively. These reductions were achieved by 45.3%, 25.2%, and 5.4% of participants in the PBO group, respectively (n=349).

Figure 1. Reduction in moderate-to-severe VMS at week 4

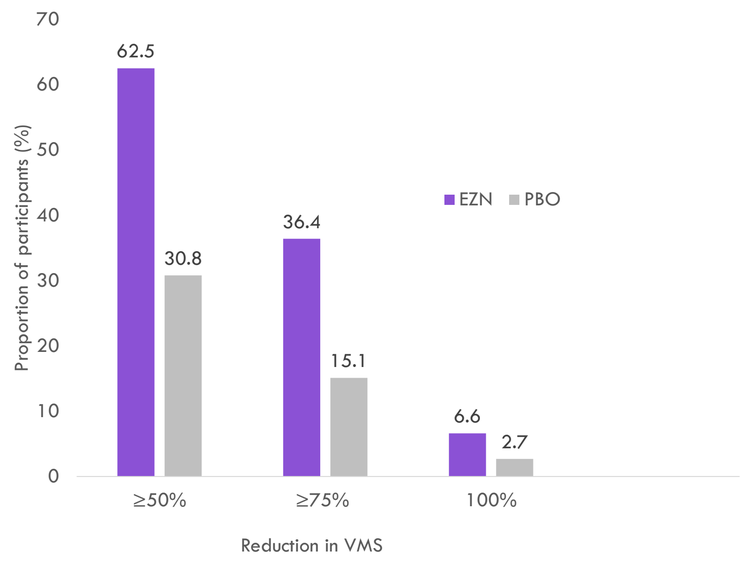
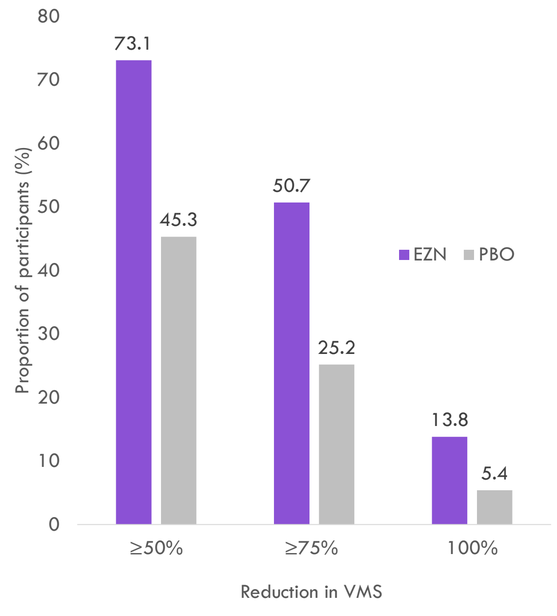


Figure 2. Reduction in moderate-to-severe VMS at week 12



- By week 26, when all participants were receiving EZN (n=452), the proportion of participants achieving a reduction in moderate-to-severe VMS frequency of ≥50% was >80%.

CONCLUSIONS

The findings further showed that EZN relieves the frequency of moderate-to-severe VMS among postmenopausal women

Most postmenopausal women treated with EZN achieved a reduction of ≥50% in the frequency of moderate-to-severe VMS within 4 weeks

Almost 75% of women achieved a ≥50%, ≥75%, or 100% reduction in moderate-to-severe VMS frequency after 12 weeks of EZN treatment

By week 26, when all participants were receiving EZN, >80% achieved a reduction in moderate-to-severe VMS frequency of ≥50%

ACKNOWLEDGEMENTS

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REFERENCES

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

DISCLOSURES

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. 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. Nick Panay has lectured and acted in an advisory capacity for: Abbott, Astellas, Bayer, Besins, Gedeon Richter, Mithra, Novo Nordisk, SeCur, Theramex, and Viatris. 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.. Claudio Soares has received research grants from: Ontario Brain Institute, Clairvoyant Therapeutics, Eisai Inc. and performed consultancy work for: Otsuka, Bayer, Eisai, Diamond Therapeutics. 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. Rebecca Thurston serves on the advisory boards for: Astellas, Bayer HealthCare AG, and Hello Therapeutics. Senka Djordjevic and Lineke Zuurman are employees of Bayer CC AG. Claudia Haberland and Maja Francuski are employees of Bayer AG. Andrew Trigg and Nazanin Haseli-Mashhadi are employees of Bayer PLC.