

Efficacy of elinzanetant in VMS associated with endocrine therapy: OASIS-4 subgroup analyses

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INTRODUCTION

→ Vasomotor symptoms (VMS) and sleep disturbances are common in women taking endocrine therapy (ET) for hormone receptor-positive (HR+) breast cancer. These may negatively impact health-related quality of life (HRQoL) and adherence to ET, potentially influencing breast cancer treatment outcomes.¹⁻⁴

Currently, there are few efficacious treatment options available for treating VMS in this population and none approved for this indication.¹

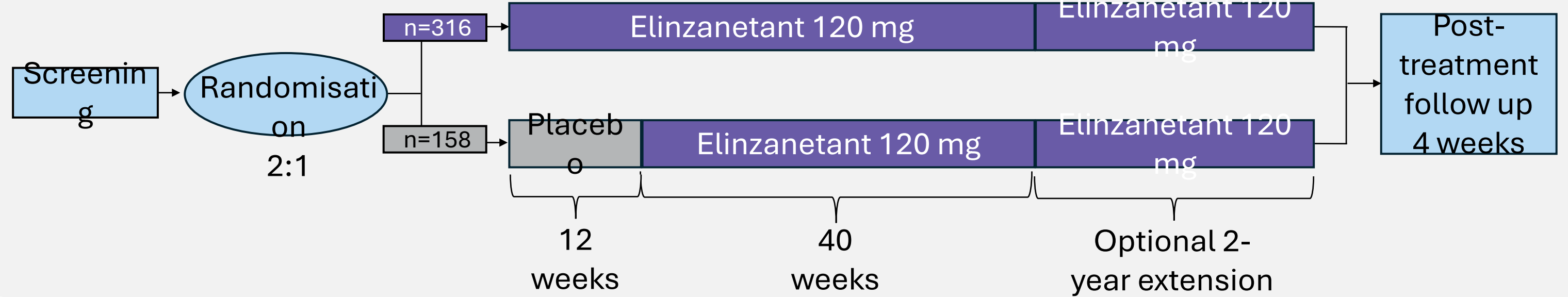
Elinzanetant, a dual neurokinin-targeted therapy (NK-1 and NK-3 receptor antagonist), improved VMS, sleep disturbances, and menopause-related quality of life in women undergoing natural or surgically induced menopause in the Phase III OASIS-1, -2, and -3 trials.^{5,6}

OASIS-4 additionally demonstrated that elinzanetant significantly reduced VMS frequency in women taking ET for HR+ breast cancer compared with placebo. **This analysis evaluated the effect of elinzanetant in pre-specified body mass index (BMI) and smoking history subgroups in OASIS-4.**

METHODS

→ OASIS-4 (NCT05587296) included women aged 18–70 years experiencing ≥35 moderate-to-severe VMS per week while receiving ET for the treatment or prevention of HR+ breast cancer (**Figure 1**).

Figure 1. Study design



In descriptive analyses, participants were evaluated by BMI (<18.5 [elinzanetant: n=2; placebo: n=2], 18.5 to <25 [n=145; n=61], 25 to <30 [n=111; n=60], ≥30 kg/m² [n=58; n=35]) and smoking history (never [n=201; n=108], former [n=71; n=33], current [n=44; n=17]).

Subgroup categories with ≤5 participants were not included in the analyses. Mean daily moderate-to-severe VMS frequency at baseline and changes from baseline to week 12 were compared descriptively across subgroups.

RESULTS

BMI subgroups

→ At baseline, means of average daily moderate-to-severe VMS frequency in the elinzanetant and placebo groups were considered similar across BMI subgroups (**Figure 2**). Mean reductions from baseline to week 12 in mean daily moderate-to-severe VMS frequency were numerically greater with elinzanetant than with placebo across all BMI subgroups (**Figure 3**). Safety findings were also considered similar across BMI subgroups and the overall OASIS-4 population.

Figure 2. BMI subgroups baseline mean (SD) daily moderate-to-severe VMS frequency

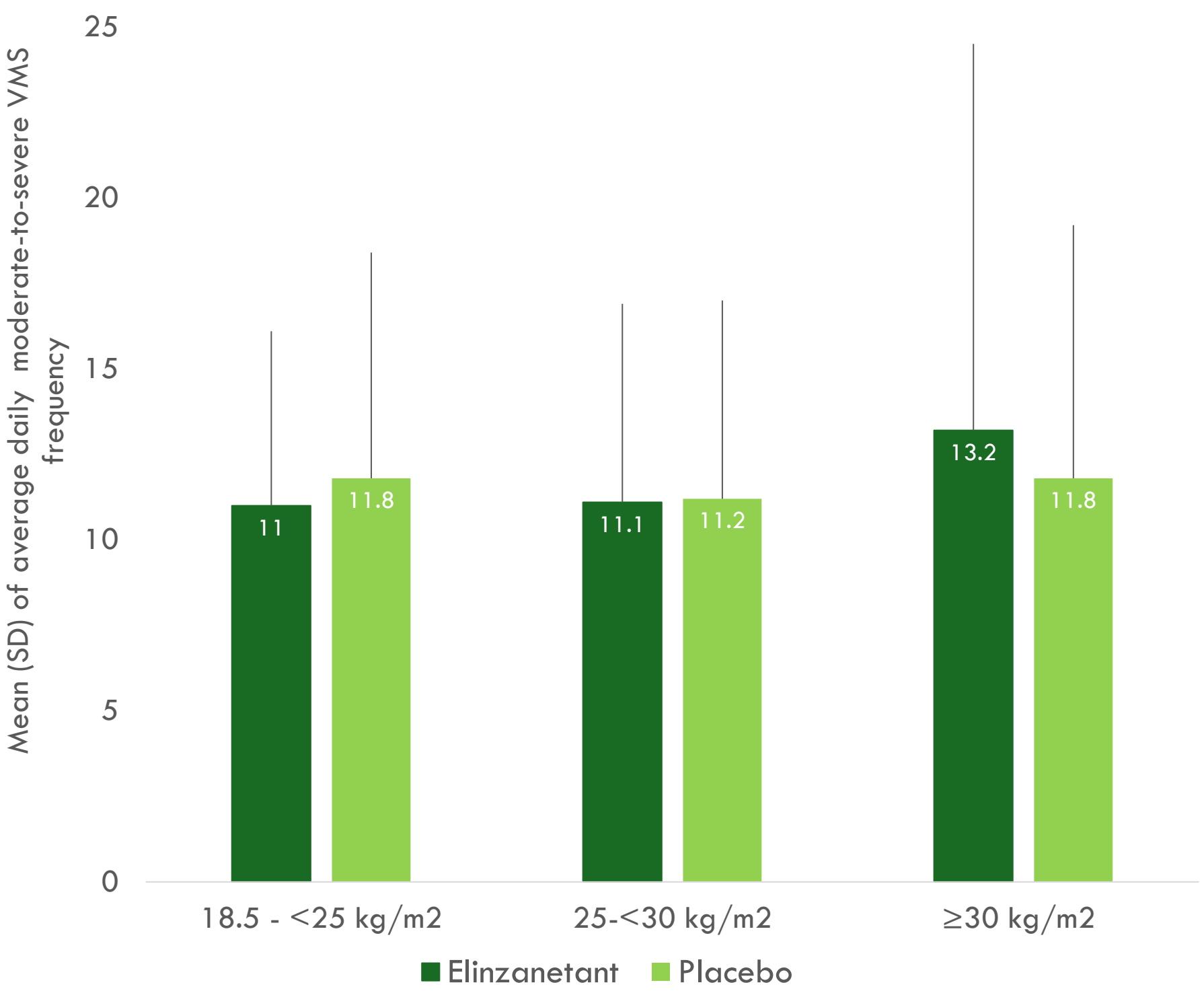
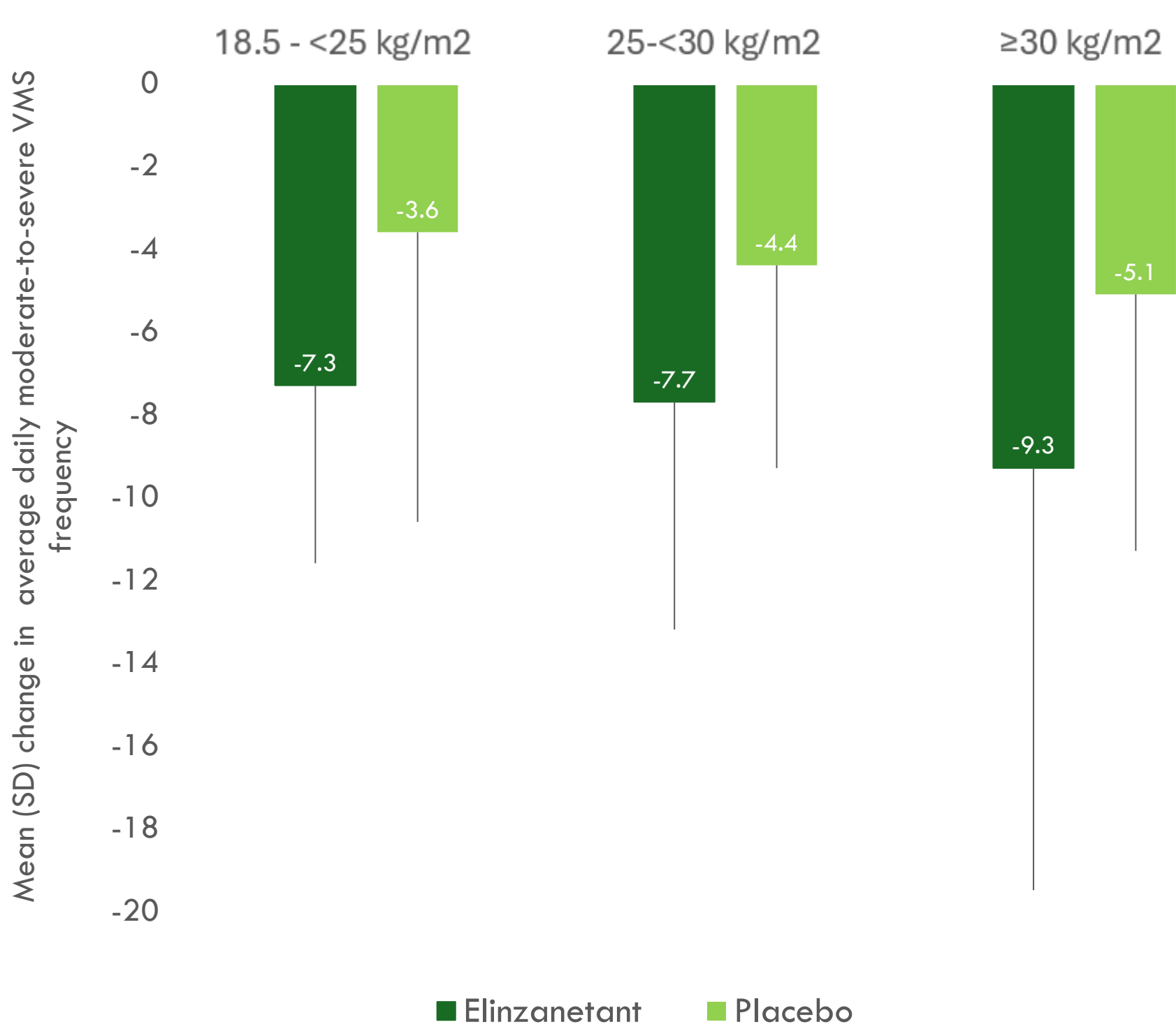


Figure 3. BMI subgroups mean (SD) numerical change in average daily moderate-to-severe VMS frequency from baseline to week 12



Smoking history subgroups

→ At baseline, means of average daily moderate-to-severe VMS frequency in the elinzanetant and placebo groups were considered similar across subgroups of never, former, and current smokers (**Figure 4**). At week 12, mean reductions from baseline in mean daily moderate-to-severe VMS frequency were numerically greater with elinzanetant than with placebo across all smoking history subgroups (**Figure 5**). Safety findings were also considered similar across smoking subgroups and the overall OASIS-4 population.

Figure 4. Smoking history subgroups baseline mean (SD) daily moderate-to-severe VMS frequency

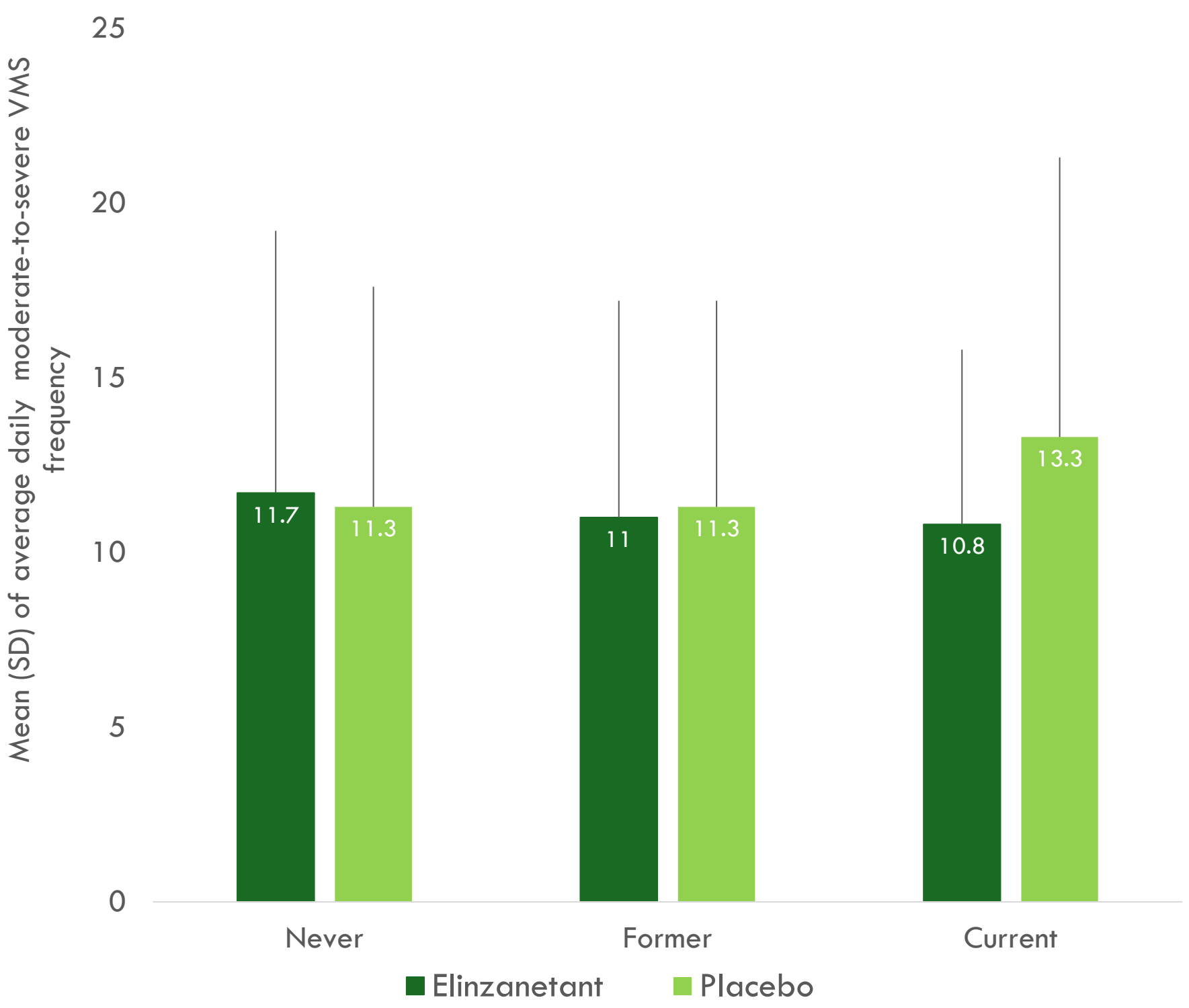
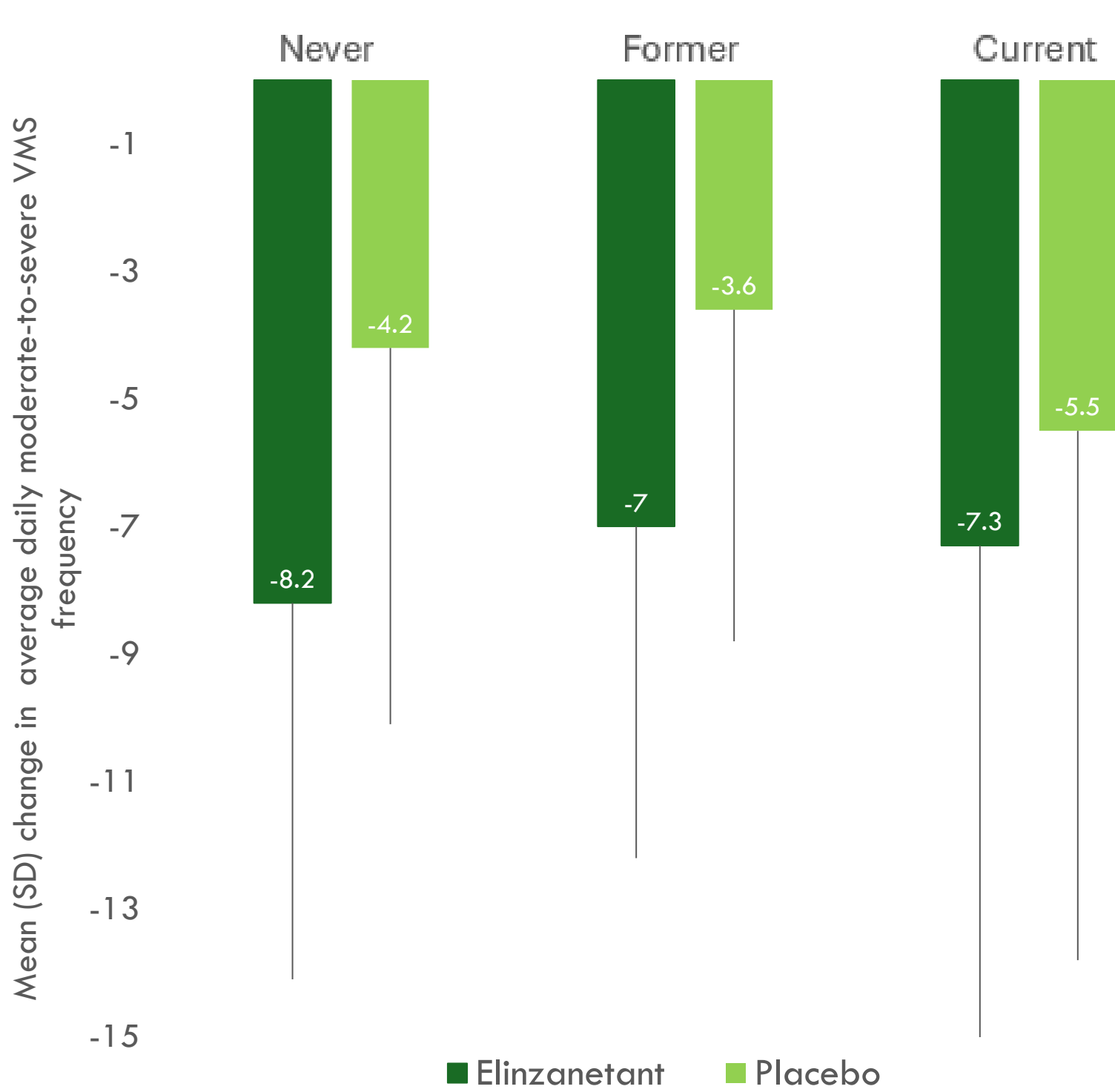


Figure 5. Smoking history subgroups mean (SD) numerical change in average daily moderate-to-severe VMS frequency from baseline to week 12



CONCLUSIONS

Elinzanetant is the first neurokinin-targeted therapy to demonstrate efficacy in reducing VMS in women receiving ET for HR+ breast cancer and consistently demonstrated greater numerical reductions than placebo in moderate-to-severe VMS frequency across the analysed BMI and smoking history subgroups.

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DISCLOSURES

→ Fatima Cardoso declares paid consultancy for: Amgen, Astellas/Medivation, AstraZeneca, Bayer, Celgene, Daiichi-Sankyo, Eisai, GE Oncology, Genentech, Gilead, GlaxoSmithKline, Iqvia, MacroGenics, Medscape, Merck-Sharp, Merus BV, Mylan, Mundipharma, Novartis, Pfizer, Pierre-Fabre, prIME Oncology, Roche, Sanofi, Samsung Bioepis, Seagen, Teva, Touchime. Donal J Brennan has acted in an advisory capacity for Merck, GSK, AstraZeneca, Bayer, Astellas; received research funding from Pfizer, GSK, AstraZeneca, Bayer; and received Honoraria from Bayer, Medtronic, Olympus, MSD, RAND Biotech. Paula Briggs has received honoraria from: Bayer, MSD (Organon), Theramex, Besins, Meda, Mylan, Viatrix, GSK, Gedeon Richter, Consilient, Astellas, Actavis, Shionogi and Pfizer. She has been supported to attend meetings by: Gedeon Richter, Bayer, MSD, Shionogi, and Theramex. Gilbert Donders has acted in an advisory capacity for and/or received research funding from Medinova, Bayer, Astellas, GSK, MSD, Mycovia, Purna pharmaceuticals, Limmatech, and Gedeon Richter. Nick Panay has lectured and acted in an advisory capacity for: Abbott, Astellas, Bayer, Besins, Gedeon Richter, Mithra, Novo Nordisk, SeCur, Theramex, and Viatrix. Maja Francuski, Claudia Haberland, and Christian Seitz are employees of Bayer AG. Nazanin Haseli Mashhadi is an employee of Bayer plc. Cecilia Caetano and Lineke Zuurman are employees of Bayer CC AG. Kaisa Laapas is an employee of Bayer Oy.