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Poster Presentation

Excellent cycle control of an estetrol 15 mg and drospirenone 3 mg combined oral contraceptive in the E4Freedom EU/RU phase 3 trial

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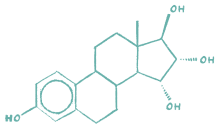

Objective: To assess cycle control and the bleeding pattern associated with estetrol (E4) 15 mg / drospirenone (DRSP) 3 mg in a 24/4-day regimen, during 1 year of usage.

Methods: This multicentre, open-label, phase 3 trial was conducted in 69 centres across Europe and Russia. Healthy women 18-50 years with regular cycles and a BMI between 18 and 35 kg/m2 enrolled for up to 13 consecutive cycles. We evaluated cycle control and bleeding patterns based on e-diaries which subjects completed daily to document vaginal bleeding and/or spotting. Bleeding was defined as blood loss that required the use of sanitary protection with a tampon, pad or, pantyliner, while spotting was defined as minimal blood loss that did not require new use of protection. One or more consecutive bleeding and/or spotting days bounded on either end by 2 bleeding and/or spotting-free days was defined as a bleeding/spotting episode. Descriptive intention-to-treat analyses were performed to assess cycle control and reasons for study discontinuation.

Results: Of 1,577 subjects, 1,553 (98.5%) started study treatment of whom 1,353 (87%) were 18-35 years and 1,218 (77%) completed 13 cycles. The most common reasons for discontinuation were adverse events (AEs) unrelated to bleeding (n=104, 6.0%), consent withdrawal (n=86, 4.9%) and AEs related to bleeding (n=54, 3.1%). The mean number of scheduled ("withdrawal") bleeding and spotting days per cycle was 2.6 and 2.4, respectively. The proportion of subjects experiencing unscheduled bleeding and/or spotting decreased over time (Cycle 1 23.5%; Cycle 2 19.2%; Cycle 6 15.6%), and remained 12.8%-15.8% for Cycles 7-13. Most of these episodes were spotting with a mean number of unscheduled bleeding and spotting days in Cycle 1 of 0.2 and 0.8, respectively, after which both values gradually decreased to 0.1 and 0.4, respectively, in Cycle 12. The proportion of women with cycles with no scheduled ("withdrawal") bleeding and/or spotting episodes varied between 5.6% and 8.1% (mean 7.9%).

Conclusion: E4/DRSP in a 24/4 regimen displayed excellent cycle control and a favorable bleeding pattern.