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EFFICACY AND SAFETY OF THE SELECTIVE PROGESTERONE RECEPTOR MODULATOR (PRM) VILAPRISAN â€“ DATA FROM THE PHASE 2 ASTEROID 2 STUDY

Gemzell-Danielsson K (SE) [1], Ramirez F (DE) [2], Petersdorf K (DE) [3], Faustmann T (DE) [4], Seitz C (DE) [5]

Context:
Selective PRMs can stop heavy menstrual bleeding (HMB), induce amenorrhea and reduce uterine fibroid (UF) volume.

Objective:
In ASTEROID 2, efficacy and safety of vilaprisan (VPR), a novel highly selective PRM, was assessed in women with UF.

Methods:
A multicenter, double-blind, multi-arm, phase 2 study of treatment with VPR, ulipristal acetate (UPA), or placebo for one or two 12-week treatment periods. ASTEROID 2 also compared different VPR regimens of up to 24 weeks in duration. Outcomes at the end of the first treatment period (12 weeks) are reported.

Patients
Women with at least one UF â‰¥3 cm and HMB >80 mL documented by menstrual pictogram (MP) were randomized to treatment.

Interventions:
VPR 2 mg once daily (OD), UPA 5 mg OD, or placebo.

Main Outcome Measures:
Amenorrhea (<2 mL in the last 28 days of treatment) and HMB response (<80 mL and >50% reduction in bleeding from baseline during the third 28-day reference period of the treatment period) were measured by MP. Change in volume of the largest fibroid from baseline to the end of the treatment period was assessed by MRI and ultrasound. Adverse events and laboratory parameters were monitored, and the endometrium was assessed by biopsy.

Results:

[1] Karolinska Institutet, [2] inventiv Health, [3] Bayer AG, [4] Bayer AG, [5] Bayer AG

164 women completed the first 12 weeks of treatment (VPR n=70; UPA n=74; placebo n=20). After 12 weeks, amenorrhea was observed in 81.4% of women with VPR (95% confidence interval [CI] 70.3–89.7%), 71.6% with UPA (95% CI 60.0–81.5%), and 5.0% with placebo (95% CI 0.1–24.9%). There were considerable reductions in HMB, with 95.7% of women treated with VPR assessed as responders, 86.5% with UPA, and 40.0% with placebo. In the active treatment groups, marked decreases in the mean volume of the largest fibroid were observed. VPR treatment was associated with clinically meaningful decreases in symptom severity and improvements in health-related quality of life. No unexpected safety issues were identified. Endometrial biopsy was performed after the second treatment period, and showed no unexpected findings.

Conclusions:
In ASTEROID 2, VPR 2 mg effectively induced amenorrhea, reduced HMB, and decreased UF size. VPR was well tolerated and no unexpected findings were observed in the endometrial safety monitoring. Further ASTEROID 2 efficacy and safety data for up to 24 weeks of VPR treatment are pending.