IMPACT OF ELAGOLIX ON QUALITY OF LIFE MEASURED BY EQ-5D-5L IN WOMEN WITH HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE FIBROIDS: EVIDENCE FROM A PHASE 2B RANDOMIZED TRIAL

Abstract ID : 3287
Submitted by : Alice Wang the 2018-01-30 18:59:42
Category : 17- Uterine fibroids treatments
Typology : Communication orale / Oral communication
Status : Validated
Authorisation to disclose : Yes/Oui

Introduction: Heavy menstrual bleeding (HMB) is one of the most bothersome symptoms associated with uterine fibroids (UF) and has a significant impact on patients' health-related quality of life (HRQOL). This study reports the impact of Elagolix, a novel oral gonadotropin-releasing hormone antagonist, on HRQOL in patients with HMB in a Phase 2b trial, measured by EQ-5D-5L, a standardized preference-based HRQOL questionnaire.

Patients and methods: Premenopausal women aged 18 to 51 years with HMB (defined as > 80 mL blood loss per menstrual cycle) associated with UF were enrolled in a Phase 2b, randomized, double-blind, multicenter, placebo-controlled, parallel group trial with 6-month treatment of Elagolix. The trial consisted of two cohorts: elagolix 300 mg BID in cohort 1 and elagolix 600 mg QD in cohort 2. Each cohort had four arms: placebo, elagolix (E) alone, and two elagolix plus add-back arms (low dose [LDA], estradiol [E2] 0.5 mg/norethindrone acetate 0.1 mg [NETA], and standard dose [SDA], 1.0 mg E2/0.5mg NETA). HRQOL was assessed using a 0-100 visual analogue scale (VAS) in the EQ-5D-5L questionnaire at baseline and after 6 months of treatment. Least square (LS) changes in mean EQ-5D-5L index scores (range 0-1 with 0 corresponds to death and 1 to perfect health) at month 6 from baseline were compared between each elagolix dose and placebo using ANCOVA models, adjusting for baseline differences.

Results: A total of 258 women in cohort 1 were included in the analysis. Mean EQ-5D-5L index scores at baseline versus (vs) month 6 were 0.82 vs 0.81, 0.80 vs 0.88, 0.83 vs 0.90 and 0.81 vs 0.87 for placebo, E alone, E+LDA, and E+SDA arms, respectively. Compared to placebo at month 6, increases in LS mean utility value in all Elagolix treatment arms were significantly higher (better HRQOL), by 0.08 (SE 0.03) in E alone and E+LDA arms (p<0.01), and by 0.06 (SE 0.03) in E+SDA (p<0.05). Mean HRQOL VAS scores increased from 79.0 at baseline to 79.4 at month 6 for placebo, from 84.1 to 85.6 for E alone, from 80.4 to 80.7 for E+LDA, and from 74.3 to 83.5 for E+SDA. Increases in the LS mean HRQOL VAS scores in Elagolix arms were larger than that in placebo, by 4.3 (SE 2.9) in E alone, 0.8 (SE 2.8) in E+LDA, and 5.9 (SE 2.8) the E+SDA arm (p<0.005). Results from 306 women in cohort 2 were similar.

Conclusion: Elagolix with or without add-back therapy improved HRQOL among women with HMB associated with UF.

Keywords : Uterine fibroids, quality of life
Authors :
References : , , ,

Authors

Sanjay Agarwal 1, Ahmed Soliman 2, Alice Wang 2, Charlotte Owens 3,
1. Department of Reproductive Medicine, University of California San Diego, La Jolla CA, UNITED STATES
2. Health Economics and Outcomes Research, AbbVie Inc, North Chicago, UNITED STATES
3. Clinical Development, AbbVie Inc, North Chicago, UNITED STATES

Authors (raw format)
Agarwal Sanjay - email : skagarwal@ucsd.edu Institution : University of California San Diego Department : Department of Reproductive Medicine City : La Jolla CA Country : UNITED STATES Speaker : Yes
Soliman Ahmed - email : ahmed.m.soliman@abbvie.com Institution : AbbVie Inc Department : Health Economics and Outcomes Research City : North Chicago Country : UNITED STATES Speaker : No
Wang Alice - email : alice.wang@abbvie.com Institution : AbbVie Inc Department : Health Economics and Outcomes Research City : North Chicago Country : UNITED STATES Speaker : No
Owens Charlotte - email : charlotte.owens@abbvie.com Institution : AbbVie Inc Department : Clinical Development City : North Chicago Country : UNITED STATES Speaker : No