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Safety of Ospemifene, an update from real life use

N BRUYNIKS (GB)

INTRODUCTION: The Selective Estrogen Receptor Modulator (SERM) ospemifene was approved by the FDA in 2013 (as Osphena®) and in 2015 by the European Commission (as Senshio®). Based largely on concerns with other SERMs and oral oestrogen, 14 risks were identified as 'important potential risks' for ospemifene, the most well-known is VTE. The risk of VTE is increased with other SERMs and oestrogen, particularly during the first months of primary use, but not with ospemifene. The Marketing Authorisation Holder for Senshio® has a rigorous post-marketing surveillance reporting system and is performing a Post-Authorisation Safety Study (PASS) The PASS is a retrospective cohort study using data from claims databases and is to run for 5 years.

AIM: To review the safety data from real life use for the specific conditions identified as important potential risks with ospemifene, collected via pharmacovigilance reporting and the PASS.

METHODS: Post-marketing Adverse event reports from the period of 27 February 2013 to 26 August 2017 are summarised. The PASS evaluates the incidence of VTE and other important potential risks in VVA patients treated with ospemifene compared to 1) patients newly prescribed SERMs for non-cancer indications and 2) patients with untreated VVA. Current data are from the 2-year interim analysis of this study.

RESULTS: The cumulative post-marketing exposure between 26 February 2013 and 26 August 2017 is approximately 128,995 women-years. The incidence from pharmacovigilance reports of all important potential risks were well below the reported background incidence. The PASS includes 5,157 women using ospemifene, 8,143 women using other SERMs and 161,196 patients with VVA without treatment. For VTE, the incidence rates are lower in the ospemifene cohort than in the other two cohorts with no overlap in the 95% confidence intervals. Most of the secondary endpoints were observed more frequently in the untreated VVA cohort than in the ospemifene cohort.

DISCUSSION: None of the Important Potential Risks identified in the Senshio® RMP has been flagged in the post marketing spontaneous reports system. Nor have they been shown to be increased over and above the incidence of these risks in a population using comparator SERMs or in patients with a diagnosis of VVA without any treatment.