

# **Linzagolix outcomes in women with concurrent Endometriosis and Adenomyosis: A post-hoc analysis of the EDELWEISS-3 and 6 trials**

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## **Introduction/Background**

Endometriosis, a chronic inflammatory disorder characterised by troublesome dysmenorrhoea (DYS) and pelvic pain often co-exists with adenomyosis, a condition characterised by the infiltration of endometrial tissue into the uterine wall. Here, we evaluated outcomes of patients with co-existing endometriosis and adenomyosis treated with linzagolix in the EDELWEISS-3 and 6 trials.

## **Materials and Methods**

EDELWEISS-3 was a multi-center, randomized, double-blind phase 3 trial evaluating linzagolix versus placebo for endometriosis-associated pain. Patients were randomised to receive linzagolix 75mg, 200mg plus add-back therapy (1mg estradiol/0.5mg norethindrone acetate), or placebo for 6-months. Upon completion, patients were then invited to continue treatment with linzagolix for a further 6-months in the EDELWEISS-6 trial. This post-hoc analysis examines outcomes in patients with endometriosis (Endo) alone versus those with concurrent adenomyosis (Endo+Adeno) in the EDELWEISS trials.

## **Results**

Of the 484 patients enrolled, 145 (30%) had concurrent adenomyosis. For DYS, a greater proportion of patients in the Endo+Adeno group (78.4%; OR:11.24,  $p<0.001$ ) showed improvement with linzagolix 200mg+ABT compared to the Endo group (69.5%; OR:7.01,  $p<0.001$ ) at 3-months, with sustained improvements observed at 6 and 12-months. In the 75mg arm, DYS improvements were generally lower. For NMPP, linzagolix 200mg+ABT improved symptoms in 47.6% (OR:2.05,  $p=0.021$ ) of the Endo group and 49% (OR:1.92,  $p=0.243$ ) of the Endo+Adeno group at 3-months, with statistical significance in the Endo group only. By 6-months however, significant improvements in NMPP were observed in both Endo+Adeno and Endo groups ( $p=0.026$  and  $p=0.034$ , respectively) which was maintained up to 12-months. Linzagolix 75mg showed no significant improvement in NMPP in either group.

## **Conclusion**

Linzagolix 200mg+ABT significantly improved DYS in patients with concurrent endometriosis and adenomyosis, indicating this higher dose may be optimal for this subgroup. Further investigation is warranted.

## **Key words**

Linzagolix, adenomyosis, endometriosis