

## **Long-term extension study to assess the effect of Linzagolix in women with endometriosis-associated pain (EDELWEISS-6 trial)**

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### **Introduction**

Linzagolix is a GnRH antagonist that is currently under development for the reduction of pain associated with endometriosis. In this extension study (EDELWEISS-6), we assessed the long-term effects of linzagolix in women with moderate to severe endometriosis-associated pain (EAP) who have completed the phase 3, double-blind, placebo-controlled EDELWEISS-3 trial.

### **Materials and Methods**

Following completion of the principal EDELWEISS-3 trial, participants were invited to continue treatment for a further six months with either linzagolix 75mg or 200mg plus hormonal add-back therapy (1mg estradiol/0.5mg norethindrone acetate) for their EAP. Co-primary endpoints were a clinically meaningful reduction in dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) up to month 12. Key secondary endpoints assessed sustained efficacy in dyschezia, overall pelvic pain (OPP) and pain interference with daily activities up to 12-months.

### **Results**

Of the 484 women completing EDELWEISS-3, 353 enrolled and were analysed in the EDELWEISS-6 study. At the outset of this extension study (at month-6), 84.7% of women in the linzagolix 200mg+ABT group and 49.6% in the linzagolix 75mg group showed a clinically meaningful reduction in DYS, increasing to 91% and 55.9% by month-12, respectively. For NMPP, response rates rose from 61% and 54.0% at month 6 to 67.6% and 59.5% by month-12 for the 200mg+ABT and 75mg groups, respectively. Additional improvements in dyschezia, OPP, and pain interference with daily activities were observed from month-6 to -12 with both treatment arms. Hot flushes (3.4–6.9%) were the most common adverse event, and bone mineral density change from baseline was <2% at month-12 across all groups.

### **Conclusion**

Improvements in DYS and NMPP observed at month-6 further increased by month-12 in both the linzagolix 75mg and 200mg+ABT groups. Similarly, efficacy on key secondary endpoints demonstrated at month 6 continued to improve up to month-12. Overall, linzagolix was well-tolerated over the 12-months treatment course in EDELWEISS-3 and -6 trials.

### **Key words**

Linzagolix, GnRH antagonist, Endometriosis