22 April 2022 Rev.1
EMA/CHMP/209022/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Yselty

linzagolix choline

On 22 April 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yselty, intended for the treatment of symptoms of uterine fibroids.[2]

The applicant for this medicinal product is ObsEva Ireland Ltd.

Yselty will be available as 100 mg and 200 mg film-coated tablets. The active substance of Yselty is linzagolix choline, a selective, non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist that binds to the GnRH receptors in the pituitary gland, modulating the hypothalamic-pituitary-gonadal axis. Yselty can be administered with or without concomitant hormonal add-back therapy depending on the clinical setting. The ATC code is yet to be assigned.

As uterine fibroids are associated with heavy menstrual bleeding, the main benefit of Yselty is a reduced monthly blood loss. The most common side effects are hot flushes and headaches.

The full indication is:

> Yselty is indicated for treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

Yselty should be prescribed by physicians experienced in the treatment of uterine fibroids.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] The CHMP had initially adopted an opinion on 16 December 2021. Following a request from the European Commission, the Committee readopted its opinion on 22 April 2022.

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