24 March 2022
EMA/CHMP/138725/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Camcevi

leuprorelin

On 24 March 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 Camcevi, intended for the treatment of the cancer of the prostate in adult men when the cancer is 'hormone-dependent', which means that it responds to treatments that reduce the levels of the hormone testosterone.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Camcevi will be available as a 42 mg prolonged-release suspension for injection. The active substance of Camcevi is leuprorelin, a gonadotropin-releasing hormone receptor analogue (ATC code: L02AE02). Leuprorelin inhibits pituitary gonadotropin secretion and suppresses testicular steroidogenesis in males. Continuous release of leuprorelin results in below-castration ($\leqslant$ 50 ng/dL) levels of testosterone in males.

The benefit of Camcevi is the achievement and maintenance of very low levels of testosterone ($\leq$ 0.5 ng/mL) which was demonstrated throughout the 12-month treatment period. The most common side effects are hot flush, injection site pain and fatigue.

Camcevi is a hybrid medicine[2] of Eligard, which has been authorised in the EU since 23 November 2003. Camcevi contains the same active substance as Eligard but is supplied as a ready-to-use drug product in contrast to Eligard, which requires pre-mixing prior to subcutaneous injection. The salt in Camcevi (leuprorelin mesilate) is also different to that in Eligard (leuprorelin acetate).

Studies have demonstrated the satisfactory quality of Camcevi, and its bridging with the reference product Eligard was established based on comparability of testosterone suppression levels.

The full indication is:

> CAMCEVI is indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy.

[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] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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Camcevi should be prescribed by physicians experienced in the treatment of prostate cancer.

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.