15 November 2018
EMA/CHMP/784876/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Erleada

apalutamide

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Erleada, intended for the treatment of non-metastatic castration resistant prostate cancer. The applicant for this medicinal product is Janssen-Cilag International N.V.

Erleada will be available as 60-mg tablets. The active substance of Erleada is apalutamide, a selective androgen receptor inhibitor (ATC code: L02BB05) that binds directly to the ligand binding domain of the androgen receptor.

The benefits with Erleada are its ability to delay metastatic disease. The most common side effects are fatigue, skin rash, weight decrease, arthralgia and falls.

The full indication is: "Erleada is indicated in adult men for the treatment of non-metastatic castration resistant prostate cancer (NM CRPC) who are at high risk of developing metastatic disease". It is proposed that Erleada be prescribed by physicians experienced in the use of anti-cancer therapies.

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

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