30 January 2020
EMA/32437/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nubeqa

darolutamide

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nubeqa, intended for the treatment of prostate cancer. The applicant for this medicinal product is Bayer AG.

Nubeqa will be available as 300-mg film-coated tablets. The active substance of Nubeqa is darolutamide, an androgen receptor inhibitor (ATC code: L02BB06) that binds directly to the receptor ligand binding domain.

The benefits with Nubeqa are its ability to delay metastatic disease in patients with non-metastatic castration-resistant prostate cancer. The most common side effect is fatigue.

The full indication is:

"NUBEQA is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease".

It is proposed that Nubeqa be prescribed by a specialist physician experienced in 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.

[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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