13 October 2022
EMA/CHMP/793918/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pluvicto

lutetium (^{177}Lu) vipivotide tetraxetan

On 13 October 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 Pluvicto, intended for the treatment of prostate cancer. The applicant for this medicinal product is Novartis Europharm Limited.

Pluvicto will be available as a 1000 MBq/ml solution for injection/infusion. The active substance of Pluvicto is lutetium (^{177}Lu) vipivotide tetraxetan, a therapeutic radiopharmaceutical (ATC code: V10XX05), which binds to cancer cells expressing the prostate-specific membrane antigen and delivers therapeutic radiation to the targeted cells, causing DNA damage that can lead to their death.

The benefits of Pluvicto are improvements in overall survival and radiographic progression free survival compared to best standard of care, as observed in a randomised, multicentre, open-label phase III study. The most common side effects are fatigue, dry mouth, nausea, anaemia, decreased appetite and constipation.

The full indication is:

> Pluvicto in combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition is indicated for the treatment of adult patients with progressive prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane based chemotherapy.

Pluvicto should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings (see SmPC section 6.6) and after evaluation of the patient by a qualified physician.

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

[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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