13 October 2022
EMA/CHMP/742076/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Locametz

gozetotide

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 Locametz, intended for the diagnosis of prostate cancer. The applicant for this medicinal product is Novartis Europharm Limited.

Locametz will be available as a 25 µg kit for radiopharmaceutical preparation. The drug substance of Locametz is gozetotide. Gallium (^{68}Ga) gozetotide, obtained after radiolabelling of Locametz with gallium-68, is a diagnostic radiopharmaceutical for tumour detection (ATC code: V09IX14) that binds to cells that express prostate specific membrane antigen (PSMA). This includes malignant prostate cancer cells, which overexpress PSMA.

The benefits of Locametz are its potential to diagnose prostate cancer during primary staging and of prostate cancer recurrence in patients with biochemical recurrence, and its use for patient selection for PSMA-targeted treatment. The most common side effects are fatigue, nausea, constipation and vomiting.

The full indication is:

> Locametz, after radiolabelling with gallium 68, is indicated for the detection of prostate specific membrane antigen (PSMA) positive lesions with positron emission tomography (PET) in adults with prostate cancer (PCa) in the following clinical settings:
>
> - Primary staging of patients with high risk PCa prior to primary curative therapy,
> - Suspected PCa recurrence in patients with increasing levels of serum prostate specific antigen (PSA) after primary curative therapy,
> - Identification of patients with PSMA positive progressive metastatic castration resistant prostate cancer (mCRPC) for whom PSMA targeted therapy is indicated (see section 4.4).

Locametz should only be administered in a designated nuclear medicine facility by trained healthcare

[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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professionals with technical expertise in using and handling nuclear medicine imaging agents.

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.