25 May 2023
EMA/CHMP/235199/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pylclari

piflufolastat (^{18}F)

On 25 May 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pylclari, intended for the diagnosis of prostate cancer. The applicant for this medicinal product is Curium Pet France.

Pylclari will be available as a 1000 MBq/mL and 1500 MBq/mL solutions for injection. The active substance of Pylclari is piflufolastat (^{18}F), a diagnostic radiopharmaceutical for tumour detection (ATC code: V09IX16). Piflufolastat is a fluorine-18 labeled small-molecule prostate-specific membrane antigen (PSMA) inhibitor that enables positron emission tomography. It binds to cells expressing PSMA, including malignant prostate cancer cells which overexpress PSMA.

The benefit of Pylclari is its potential to diagnose prostate cancer during primary staging of patients at high risk and in the staging of patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) as supported by three prospective, open-label clinical studies. The most common side effects are headache and dysgeusia.

The full indication is:

> This medicinal product is for diagnostic use only.
>
> Pylclari 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 initial curative therapy,
> - To localize recurrence of PCa in patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) levels after primary treatment with curative intent.

Pylclari should be used in designated nuclear medicine facilities only and should only be handled by authorised personnel.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.