SUMMARY

(18F) piflufolastat

PYLCLARI 1 000 MBq/mL and 1 500 MBq/mL

solution for injection

First listing

Original French opinion adopted by the Transparency Committee on 28 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the MA indication: “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 localise recurrence of PCa in patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) levels after primary treatment with curative intent.”

Transparency Committee’s conclusions

Clinical Benefit

Primary staging of patients with high-risk PCa prior to initial curative therapy

- Prostate cancer is a serious, life-threatening disease.
- This is a diagnostic medicinal product.
- In view of the diagnostic performance data with (^{18}F) piflufolastat PET in cohort A of the OSPREY study and despite the absence of robust data relative to the impact on patient management, the efficacy/adverse effect ratio is high for the primary staging of patients with high-risk PCa prior to initial curative therapy.
- There are diagnostic alternatives, which are mentioned in section 5.2. of the opinion in French

➔ (^{18}F) piflufolastat PET represents an additional alternative for the primary staging (optional examination) of patients with high-risk PCa prior to initial curative therapy.

➔ Public health benefit

Considering:

- the seriousness and high incidence of prostate cancer;
- the partially met medical need for the primary staging of patients with high-risk PCa prior to initial curative therapy with the abovementioned available alternatives;
- the absence of evidence of an additional impact on mortality, morbidity or quality of life compared to the available alternatives;
- the lack of additional impact on the care and/or life pathway;

PYLCLARI ((^{18}F) piflufolastat) is unlikely to have an additional impact on public health.

Suspected recurrence of PCa in patients with increasing PSA levels after primary treatment with curative intent

➔ Prostate cancer is a serious, life-threatening disease.

➔ This is a diagnostic medicinal product.

➔ In view of the diagnostic performance data with (^{18}F) piflufolastat PET in cohort B of the OSPREY study and in the CONDOR study, of demonstration of the superiority versus (^{18}F) fluorocholine in the PYTHON study, and despite the absence of findings relative to the impact on patient management based on clinically relevant criteria, the efficacy/adverse effect ratio is high in the event of suspected recurrence of PCa in patients with increasing PSA levels after primary treatment with curative intent.

➔ There are diagnostic alternatives, which are mentioned.

➔ (^{18}F) piflufolastat PET is a first-line examination, in the same way as RADELUMIN and LOCAMETZ, in the event of suspected recurrence of PCa in patients with increasing PSA levels after primary treatment with curative intent, in view of the diagnostic alternatives.

➔ Public health benefit

Considering:

- the seriousness and high incidence of prostate cancer;
- the partially met medical need in the event of suspected recurrence of PCa in patients with increasing PSA levels after primary treatment with curative intent with the abovementioned available alternatives;
- the absence of evidence of an additional impact on mortality, morbidity or quality of life compared to the available alternatives;
- the potential improvement in the care pathway, particularly given the improvement in territorial coverage compared to [^{18}F] PSMA-1007;

PYLCLARI ((^{18}F) piflufolastat) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of PYLCLARI ((^{18}F) piflufolastat) solution for injection is substantial in the MA indication: "[…] 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 localise recurrence of PCa in patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) levels after primary treatment with curative intent."**

The Committee issues a favourable opinion for inclusion of PYLCLARI (^{18}F) piflufolastat) solution for injection in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Primary staging of patients with high-risk PCa prior to initial curative therapy

Considering:

- the diagnostic performance data with (^{18}F) piflufolastat PET in cohort A of the OSPREY study and the absence of robust data relative to the impact on patient management
- the absence of evidence of an impact on mortality, morbidity or quality of life,
- its satisfactory safety profile,
- the medical need which remains partially met.

Suspected recurrence of PCa in patients with increasing PSA levels after primary treatment with curative intent

Considering:

- the diagnostic performance data with (^{18}F) piflufolastat PET in cohort B of the OSPREY study and in the CONDOR study, demonstration of the superiority versus (^{18}F) fluorocholine in the PYTHON study and the absence of findings relative to the impact on patient management based on clinically relevant criteria,
- the absence of evidence of an impact on mortality, morbidity or quality of life,
- its satisfactory safety profile,
- the medical need which remains partially met.

The Committee deems that PYLCLARI (^{18}F) piflufolastat) solution for injection provides no clinical added value (CAV V) in the diagnostic strategy for prostate cancer, in the following clinical situations:

- **Primary staging of patients with high-risk PCa prior to initial curative therapy,**
- **To localise recurrence of PCa in patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) levels after primary treatment with curative intent.**

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