swissmedic

Summary report on authorisation dated 2 May 2025

# Pluvicto®/Pluvicto CA® (active substance: Lutetium ($^{177}$Lu) vipivotide tetraxetan)

Authorisation in Switzerland: 24 February 2023

**Solution for injection used to treat adults with advanced PSMA-positive, metastatic, castration-resistant prostate cancer that has already been treated with androgen receptor blockers and taxane-based chemotherapy.**

## About the medicinal product

Pluvicto/-CA contains the active substance lutetium ($^{177}$Lu) vipivotide tetraxetan. This consists of the radioactive substance/radionuclide lutetium-177 and vipivotide tetraxetane, which targets tumour cells.

Pluvicto/-CA is a radiopharmaceutical for the treatment of adults with prostate-specific membrane antigen-positive metastatic (spreading to other parts of the body) castration-resistant[1] prostate cancer (PSMA-positive mCRPC), in whom the disease is progressing.

Prostate cancer is a common cancer in males. If the disease metastasises and no longer responds to hormone therapy, the prognosis is often very poor.

Patients treated with Pluvicto/-CA have already received other treatments such as androgen receptor blockers and chemotherapy.

Difference between Pluvicto and Pluvicto CA:

Pluvicto and Pluvicto CA both contain the active substance lutetium ($^{177}$Lu) vipivotide tetraxetan. Pluvicto CA contains $^{177}$lutetium. This contains the impurity lutetium$^{177m}$, which can be attributed to its manufacture from lutetium$^{176}$. This $^{177}$lutetium is designated "carrier added" (CA). Pluvicto contains $^{177}$lutetium without the impurity $^{177m}$lutetium, produced using $^{176}$ytterbium. This is referred to as "non-carrier added" lutetium.

## Mode of action

Pluvicto/-CA binds specifically to PSMA, a certain protein that is found on the surface of prostate cancer cells. The radioactive portion of the medication emits therapeutic

[1] Castration-resistant: The cancer progresses, although testosterone levels in the blood are kept low with hormone therapy.

radiation directly to the cancer cells targeted, which damages DNA and destroys the cancer cells. This slows tumour growth or even kills the cancer cells.

## Use

Pluvicto/-CA requires a prescription and is a radiopharmaceutical that is manufactured as a solution for intravenous administration by injection/infusion.

It is available in a dose of 1000 MBq/mL. The recommended dose is 7400 MBq every 6 weeks (±1 week) for up to 6 doses, or until disease progression or unacceptable toxicity.

This drug is intended for exclusive use in hospitals and can be administered only in authorised facilities by qualified healthcare professionals.

## Efficacy

The efficacy of Pluvicto/-CA was investigated in the VISION study,

In this study, Pluvicto/-CA was evaluated in 831 patients with advanced, PSMA-positive, castration-resistant, metastatic prostate cancer (mCRPC) who had previously received anti-androgen therapy and taxane-based chemotherapy.

Patients received either Pluvicto/-CA together with standard therapy or standard therapy alone. The standard therapy included supportive measures such as analgesics, administration of fluids, and blood transfusions as well as hormone therapy or local radiation therapy. Cytotoxic chemotherapy was not permitted.

The study showed statistically significant improvement in overall survival (OS)[2] of 15.3 versus 11.3 months and radiographic progression-free survival (rPFS)[3] of 8.7 versus 3.4 months for patients that received Pluvicto/-CA plus standard therapy compared with those that received standard therapy only.

## Precautions, undesirable effects, and risks

Pluvicto/-CA contributes to long-term radiation exposure of the patient. Therefore, it can be associated with a higher risk of cancer.

The most common undesirable effects of Pluvicto/-CA are fatigue (43.1%), dry mouth (39.3%), nausea (35.3%), anaemia (31.8%), loss of appetite (21.2%), and constipation (20.2%).

More serious side effects include anaemia (12.9%), thrombocytopenia (low platelet count) (7.9%), and lymphocytopenia (low number of certain groups of white blood cells) (7.8%).

The risks also include myelosuppression (suppressed bone marrow function) and renal toxicity (kidney damage), which occurred more frequently in the study in patients who received Pluvicto/-CA versus those who received only the standard therapy.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

[2] Overall survival (OS) refers to the period between the start of treatment and the death of the patient.

[3]Radiographic progression-free survival (rPFS) can be defined as the time during which a patient's cancer, as assessed by imaging techniques, does not show progression. This means that in imaging examinations such as CT and MRI scans, no new tumours or enlargement of existing tumours are found.

## Why the medicinal product has been authorised

The previous treatment options for patients with advanced, PSMA-positive, metastatic, castration-resistant prostate cancer (mCRPC) include taxane-based chemotherapies or anti-androgen therapies. If these treatments fail, the survival prognosis for these patients is extremely limited.

Pluvicto/-CA is a new treatment option that binds specifically to PSMA-expressing cancer cells and emits therapeutic radiation in order to suppress tumour growth.

The VISION study showed that treatment with Pluvicto/-CA resulted in significant prolongation of survival and a delay in disease progression.

Taking all the risks and precautions into account, and based on the available data, the benefits of Pluvicto/-CA outweigh the risks. Swissmedic has therefore authorised the medicinal product Pluvicto/-CA, containing the active substance lutetium ($^{177}$Lu) vipivotide tetraxetan, for use in Switzerland.

## Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Pluvicto/-CA®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.