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Withdrawal of application to change the marketing authorisation for Pluvicto (lutetium (^{177}Lu) vipivotide tetraxetan)

Novartis Europharm Limited withdrew its application for a new use of Pluvicto in adults with prostate cancer, when the cancer is metastatic (spreading to other parts of the body), progressive, castration-resistant (worsens despite treatment to lower levels of the male sex hormone testosterone), and the cancer cells have a protein called prostate-specific membrane antigen (PSMA) on their surface (PSMA-positive prostate cancer).

The change related to extending the use of Pluvicto to adults with PSMA-positive, metastatic, castration-resistant prostate cancer (mCRPC) who have no or mild symptoms after their disease has progressed on a hormone-blocking medicine called an androgen receptor pathway inhibitor (ARPI/ARDT) and for whom chemotherapy is not yet an option.

The company withdrew the application on 23 March 2026.

What is Pluvicto and what is it used for?

Pluvicto is a medicine used to treat adults with progressive PSMA-positive mCRPC. It is used together with androgen deprivation therapy (treatment to lower male sex hormones) in adults previously treated with androgen receptor pathway inhibitors (medicines for prostate cancer), and a medicine of the group of cancer medicines known as taxanes. Androgen receptor pathway inhibitors may also be added to Pluvicto and androgen deprivation therapy.

Pluvicto has been authorised in the EU since December 2022.

It contains the active substance lutetium (^{177}Lu) vipivotide tetraxetan and is given by injection or infusion (drip) into a vein once every 6 weeks for up to 6 doses.

Further information on Pluvicto's current uses can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/pluvicto.

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What change had the company applied for?

The company applied to extend the use of Pluvicto to treat adults with PSMA-positive mCRPC who have no or mild symptoms, after their cancer has worsened despite treatment with a hormone-blocking medicine. It was intended for patients who are not yet eligible for chemotherapy.

How does Pluvicto work?

Pluvicto works by attaching to the PSMA protein found on the surface of the prostate cancer cells. The radioactivity it emits kills the cancer cells it is attached to but has little effect on neighbouring cells.

What did the company present to support its application?

The company submitted data from a study in adults with PSMA-positive, progressive, mCRPC who were previously treated with a hormone-blocking medicine and who were not yet eligible for taxane-based chemotherapy. Pluvicto was compared with a different hormone-blocking medicine. The main measure of effectiveness was how long people lived without the cancer showing signs of worsening on imaging tests (radiographic progression-free survival). The study also looked at how long people lived (overall survival).

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Pluvicto could not have been authorised for use in adults with PSMA-positive mCRPC who have no or mild symptoms and whose disease has progressed despite treatment with a hormone-blocking medicine.

Although the main study showed that the medicine could increase the time before the cancer grew or spread compared with a hormone-blocking treatment, it was not clear whether this delay provides a meaningful benefit for patients. This is because the comparator treatment, a hormone-blocking treatment, was not considered to be adequate for people with this stage of prostate cancer. In addition, treatment with Pluvicto had no impact on how long people lived overall, compared with a hormone-blocking treatment.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough information to support the application for a change to the marketing authorisation of Pluvicto.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated it withdrew based on the fact that feedback from the CHMP indicated that the Committee would not be able to conclude, on the basis of the data provided, that the benefits of the medicine outweigh its risks in the applied indication.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Pluvicto.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Pluvicto for the treatment of other diseases?

Pluvicto continues to be authorised in adults with progressive, PSMA-positive mCRPC.