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Withdrawal of application to change the marketing authorisation for Tookad (padelifporfin)

Steba biotech S.A. withdrew its application to modify the grading system and biopsy requirements for use of Tookad in the treatment of prostate cancer and extend its use from low-risk to intermediate-risk patients.

The company withdrew the application on 14 December 2021.

What is Tookad and what is it used for?

Tookad is a medicine used to treat men with low-risk prostate cancer, where the cancer affects only one side of the prostate and patients would normally be expected to survive for at least 10 years.

Tookad has been authorised in the EU since November 2017.

It contains the active substance padeliporfin and is given by injection into a vein before being activated at the site of the cancer by shining laser light along optical fibres inserted into the prostate.

Further information on Tookad's uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/tookad

What change had the company applied for?

Currently, Tookad is only for use in men with low risk prostate cancer limited to one side of the prostate, based on several criteria including a score of 6 or less in the Gleason scoring system (a measure of cancer grade), and a set of particular requirements for presence of cancer in biopsies.

The company applied for a change in the indication to use a different grading system recommended by the International Society of Urological Pathology, the ISUP grade. A Gleason score of 6 or less, as currently recommended, corresponds to an ISUP grade of 1. The company also applied for an extension of indication to allow the treatment of men with a higher grade of prostate cancer (ISUP grade 2) and to use less restrictive requirements when assessing biopsies which would allow use in more extensive disease.

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How does Tookad work?

Once activated, the active substance in Tookad, padeliporfin, triggers the production of high levels of substances known as oxygen radicals, which cause the destruction of the vessels supplying blood to the cancer followed by rapid death of the cancer cells.

What did the company present to support its application?

The company did not present any new main studies to support its application. It provided supportive information including a re-analysis of diagnostic data from the main study used for the original approval of Tookad for the treatment of prostate cancer, taking into account current guidelines and standards of classification and diagnosis of the condition.

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

The application was withdrawn after the European Medicines Agency had evaluated the 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 Tookad could not have been authorised for the treatment of prostate cancer in men with ISUP grade 2 disease, or with different disease burden at biopsy.

The Agency agreed that changing the grading system from Gleason score to ISUP grade could be acceptable in the light of current guidelines. However, it was concerned that the company had not presented any direct results from studies to show that Tookad would provide additional benefits to patients with higher grade disease (ISUP grade 2) over the current standard of care, or to justify the change in biopsy requirements to identify disease burden. Although the company had provided some supportive data, this was only enough to suggest directions for further study and was not considered sufficiently robust to justify a change of the licensed indication.

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 Tookad.

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 that it was withdrawing the application in line with its development strategy for the medicine.

Does this withdrawal affect patients in clinical trials or compassionate use programmes?

There are no consequences for patients in clinical trials or in compassionate use programmes using Tookad.

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

What is happening with Tookad in its current uses?

There are no consequences on the use of Tookad in its authorised use for low-risk prostate cancer.