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Withdrawal of application for the marketing authorisation of Nuzyra (omadacycline)

Paratek Ireland Limited withdrew its application for a marketing authorisation of Nuzyra for the treatment of infections.

The company withdrew the application on 9 October 2019.

What is Nuzyra and what was it intended to be used for?

Nuzyra was developed as a medicine for treating community-acquired bacterial pneumonia (lung infection caught outside hospitals) and bacterial infections of the skin and skin structures (the tissue immediately beneath the skin).

Nuzyra contains the active substance omadacycline and was to be available as tablets and as powder to make up an infusion (a drip).

How does Nuzyra work?

The active substance in Nuzyra, omadacycline, belongs to the class of antibiotics called tetracyclines. It works by stopping bacteria from making proteins. This stops the bacteria multiplying and helps to bring the infection under control.

What did the company present to support its application?

The company presented the results of two studies in a total of 1,390 patients with bacterial skin and skin structure infections, and one study in 660 patients with community-acquired pneumonia. In each study Nuzyra was compared with another antibiotic. The main measure of effectiveness was the number of patients in whom the infection improved enough to no longer needed antibiotic treatment.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the European Medicines Agency had considered recommending marketing authorisation for bacterial infections of the skin and skin structures.

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What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had considered recommending marketing authorisation for Nuzyra for the treatment of infections of the skin and skin structures but not for community-acquired pneumonia.

The Agency noted that other antibiotics are available that are effective for community-acquired pneumonia, a potentially life-threating condition. The single clinical study in patients with community-acquired pneumonia did not provide sufficient evidence of Nuzyra's effectiveness. The Agency considered that another study was required to establish that Nuzyra is an appropriate option for this condition.

Therefore, at the time of the withdrawal, the Agency's opinion was that it had not been shown that the benefits of Nuzyra outweighed its risks for the treatment of community-acquired pneumonia.

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

In its letter notifying the Agency of the withdrawal of the application, the company stated that it would not be commercially feasible to market Nuzyra just for the treatment of skin and skin structure infections.

Does this withdrawal affect patients in clinical trials?

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

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