27 July 2018
EMA/499771/2018
EMEA/H/C/004473

Withdrawal of the marketing authorisation application for Raligize (axalimogene filolisbac)

On 10 July 2018, FGK Representative Service GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Raligize, for the treatment of cancer of the cervix (the neck of the womb).

What is Raligize?

Raligize is a cancer medicine containing the active substance axalimogene filolisbac. It was to be available as a concentrate for making up an infusion (drip) to be given into a vein.

Raligize was developed as a type of advanced therapy medicine called a 'gene therapy product'. This is a type of medicine that works by delivering genes into the body.

What was Raligize expected to be used for?

Raligize was to be used to treat women with cervical cancer whose disease had not responded to, or had come back after, initial treatment.

How does Raligize work?

Cervical cancer is mainly caused by long-lasting infection with certain strains of the human papillomavirus (HPV), which produce proteins in infected cells that stimulate them to grow and become cancerous.

The active substance in Raligize, axalimogene filolisbac, consists of a bacterium, *Listeria monocytogenes*, that has been modified so it can produce a protein that stimulates the immune (defence) system to attack cancer cells. The bacteria in Raligize have had a gene inserted in their DNA so they can produce a new substance containing one of the HPV proteins, E7, linked to part of another protein, listeriolysin O. The linked protein is able to stimulate the immune system against E7.

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When Raligize is given to the patient, the bacteria are taken up by cells of the immune system where they stimulate it to recognize the E7 protein and attack and kill cancer cells that contain it.

What did the company present to support its application?

The company provided data from one main study involving 50 women with advanced cervical cancer, including cancer that had come back after other treatment or had spread elsewhere in the body. Results of treatment with Raligize were compared with results previously seen in similar women given other treatments for cervical cancer.

How far into the evaluation was the application when it was withdrawn?

Because Raligize is an advanced therapy medicine, it was assessed on behalf of the CHMP by the Committee for Advanced Therapies (CAT). The application was withdrawn while the CAT was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CAT was still evaluating the initial documentation provided by the company on behalf of the CHMP, it had not yet made any recommendations.

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 the withdrawal was due to initial concerns expressed by the CAT that the data from the main study would not be sufficient to support the approval of the medicine.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Raligize.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.