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Withdrawal of application for the marketing authorisation of GeGant (germanium [^{68}Ge] chloride /gallium [^{68}Ga] chloride)

ITM Medical Isotopes GmbH withdrew its application for a marketing authorisation of GeGant, a device used to obtain a solution containing radioactive gallium (^{68}Ga).

The company withdrew the application on 15 April 2024.

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

GeGant is a radionuclide generator, a device used to make a solution that contains the radioactive substance (a so-called radionuclide) gallium (^{68}Ga), which can be used by doctors to label diagnostic medicines. GeGant was not intended to be used directly in patients.

How does GeGant work?

GeGant uses radioactive germanium (^{68}Ge) to generate gallium (^{68}Ga). It is impractical to transport solutions containing gallium (^{68}Ga) for use in hospitals, because it decays too quickly. Instead, GeGant uses germanium (^{68}Ge), which is more stable, to create a gallium (^{68}Ga) solution.

Gallium (^{68}Ga) can then be used to label diagnostic medicines. When a patient is given such a radiolabelled medicine, it carries the radioactive substance to specific cells in the body, such as tumour cells. The carrier medicine gives off a small amount of radioactivity that can be detected from outside the body using a body scan known as positron emission tomography (PET). This can help doctors diagnose the disease or find where in the body these cells are.

What did the company present to support its application?

Because GeGant is not intended for direct use in patients and gallium (^{68}Ga) is not used on its own in patients, the company did not need to present data from clinical trials. The company presented medical literature and medical guidelines showing the benefits of gallium (^{68}Ga)-labelled medicines in the diagnosis of various tumours. The company also provided studies on the quality of GeGant.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. The company had not responded to the last round of questions at the time of the withdrawal.

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 some concerns and its provisional opinion was that GeGant could not have been authorised. The Agency had questions regarding compliance of the manufacturing site for the finished product with good manufacturing practice (GMP) requirements. Proof of GMP compliance for the site had been requested and was pending. The Agency also had questions about the control of impurities in the product and had requested the company to present a risk evaluation concerning the potential presence of nitrosamine impurities in the product, in line with applicable guidelines.

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 GeGant.

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 withdrew the application because it could not address EMA's concerns within the required time limit.

Does this withdrawal affect patients in clinical trials?

The company did not carry out any clinical trials.