28 May 2020
EMA/278694/2020
EMEA/H/C/005071

Withdrawal of application for the marketing authorisation of Erlotinib Accord (erlotinib)

Accord Healthcare S.L.U. withdrew its application for a marketing authorisation of Erlotinib Accord for the treatment of non-small-cell lung cancer and pancreatic cancer.

The company withdrew the application on 11 May 2020.

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

Erlotinib Accord was developed as a medicine for a type of lung cancer called non-small-cell lung cancer when it is advanced (the cancer has started to spread) or metastatic (it has already spread to other parts of the body). It was intended mainly for use in patients whose cancer cells have certain changes ('activating mutations') in the gene for a protein called epidermal growth factor receptor (EGFR).

Erlotinib Accord was also intended for use in treating locally advanced metastatic cancer of the pancreas, in combination with gemcitabine (another cancer medicine).

Erlotinib Accord contains the active substance erlotinib and was to be available as tablets to be taken by mouth.

Erlotinib Accord was developed as a 'generic medicine'. This means that Erlotinib Accord contained the same active substance as an authorised 'reference medicine' Tarceva and was intended to work in the same way. For more information on generic medicines, see the question-and-answer document here.

How does Erlotinib Accord work?

The active substance in Erlotinib Accord and Tarceva, erlotinib, works by blocking EGFRs, which are present on the cells of certain cancers. These EGFRs receive the chemical messages that encourage the cancer cells to grow and spread throughout the body. By blocking them, the medicine helps to stop the cancer from growing and spreading.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What did the company present to support its application?

Studies on the benefits and risks of the active substance are not needed for a generic medicine because they have already been carried out with the reference medicine.

As for every medicine, the company provided studies on the quality of Erlotinib Accord. The company also provided a study to investigate whether Erlotinib Accord is 'bioequivalent' to the reference medicine Tarceva. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

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. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

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 Erlotinib Accord could not have been authorised for the treatment of non-small-cell lung cancer and pancreatic cancer.

The Agency's concerns related to the way the study on bioequivalence had been carried out following an inspection for Good Clinical Practice (GCP). The inspection raised a number of concerns including the ways in which the study had been set up, supervised and modified and how the data from the study were recorded and managed.

Therefore, at the time of the withdrawal, the Agency's opinion was that the results of the study were not reliable and that the medicine could not have been authorised based on the data from the company.

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 was withdrawing its marketing application because the bioequivalence data from the study were not considered adequate.

Does this withdrawal affect patients in clinical trials?

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

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