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Withdrawal of application for the marketing authorisation of Datopotamab deruxtecan Daiichi Sankyo[1] (datopotamab deruxtecan)

Daiichi Sankyo Europe GmbH withdrew its application for a marketing authorisation of Datopotamab deruxtecan Daiichi Sankyo for the treatment of adults with non-squamous non-small cell lung cancer (NSCLC), when the disease has spread into tissues around the lungs but not to other parts of the body (locally advanced) or has spread to other parts of the body (metastatic).

The company withdrew the application on 20 December 2024.

What is Datopotamab deruxtecan Daiichi Sankyo and what was it intended to be used for?

Datopotamab deruxtecan Daiichi Sankyo was intended for the treatment of adults with non-squamous NSCLC in adults who require systemic therapy (treatment with medicines affecting the whole body as opposed to surgery or radiotherapy). It was to be used in patients with particular genetic changes who had previously been treated with platinum-based chemotherapy and another cancer medicine targeting the cancer's specific genetic change. It was also to be used in patients without particular genetic changes who had previously been treated with platinum-based chemotherapy and a cancer medicine called a PD-1 or PD-L1 inhibitor.

Datopotamab deruxtecan Daiichi Sankyo contains the active substance datopotamab deruxtecan and was to be available as a solution for infusion.

Datopotamab deruxtecan has received a positive recommendation by EMA for the treatment of breast cancer. This medicine was originally known as Datopotamab deruxtecan Daiichi Sankyo but later renamed as Datroway.

[1] Previously known as Datroway.

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How does Datopotamab deruxtecan Daiichi Sankyo work?

The active substance in Datopotamab deruxtecan Daiichi Sankyo, datopotamab deruxtecan, is made up of two active components that are linked together:

- datopotamab is a monoclonal antibody (a type of protein) that has been designed to attach to a protein called TROP2. TROP2 is present at high levels on the surface of NSCLC cells;
- deruxtecan is a toxic substance that kills cells when they divide and grow. It becomes active once datopotamab has attached to TROP2 and enters the cancer cell. Deruxtecan blocks an enzyme called topoisomerase I which is involved in copying the cell DNA needed to make new cells. When topoisomerase I is blocked, cancer cells cannot multiply and eventually die.

What did the company present to support its application?

The company presented results from one main study involving a total of 605 adults with locally advanced or metastatic NSCLC after prior treatment with platinum-based chemotherapy and either a PD-1/PD-L1 inhibitor or targeted therapy. The study compared datopotamab deruxtecan with docetaxel. The main measures of effectiveness were how long patients lived without their cancer getting worse and how long they lived overall.

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, at the time of the withdrawal, the Agency had some concerns, and its provisional opinion was that Datopotamab deruxtecan Daiichi Sankyo could not have been authorised for the treatment of NSCLC.

The Agency noted that the data on the effectiveness of Datopotamab deruxtecan Daiichi Sankyo showed a small effect of the medicine on how long patients lived without their disease getting worse. However, the results were not robust enough to prove that the medicine is effective in helping people live longer without their cancer getting worse or live longer overall. In addition, the company amended the protocol late during the study, adding uncertainty to the interpretation of results in some sub-groups of patients. In addition, the Agency had some concerns about serious side effects such as lung inflammation.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Datopotamab deruxtecan Daiichi Sankyo did not outweigh its risks.

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 decided to discontinue this application because the major objection raised could not be resolved within the timeframe.

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

The company informed the Agency that there are no consequences for patients in clinical trials or in compassionate use programmes using Datopotamab deruxtecan Daiichi Sankyo.

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