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Withdrawal of application for the marketing authorisation of Nidlegy (bifikafusp alfa/ onfekafusp alfa)

Philogen S.p.A. withdrew its application for a marketing authorisation of Nidlegy for the treatment of melanoma, a type of skin cancer.

The company withdrew the application on 24 June 2025.

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

Nidlegy was developed as a medicine to be used in adults for the treatment of melanoma that can be removed by surgery (resectable) and has spread to nearby tissues (locally advanced). Nidlegy was intended to be used as a preliminary treatment to shrink the cancer before surgery (neoadjuvant treatment).

Nidlegy contains the active substances bifikafusp alfa and onfekafusp alfa. It was to be available as a solution for injection.

How does Nidlegy work?

The active substances in Nidlegy, bifikafusp alfa and onfekafusp alfa, were expected to work by increasing the ability of the immune system (the body's natural defences) to attack the cancer.

Bifikafusp alfa consists of interleukin-2 (IL-2), a naturally occurring protein that activates certain white blood cells that can recognise and attack cancer cells. Bifikafusp alfa is linked to L19, another protein which was expected to enable the medicine to target cancer cells and not healthy tissue. Onfekafusp alfa consists of tumour necrosis factor (TNF) which disrupts the blood supply to the tumour, and is also linked to L19.

What did the company present to support its application?

The company presented data from a main study involving 256 adults with melanoma that could be removed by surgery and had spread to nearby tissues. The study compared patients who received

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
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Nidlegy before surgery with those who did not have Nidlegy before surgery. The main measure of effectiveness was the amount of time patients lived without the cancer coming back.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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 Nidlegy could not have been authorised for the treatment of melanoma.

The Agency considered that the data provided were not sufficient to demonstrate that the manufacturing and quality of the medicine met the scientific and regulatory standards required for approval.

The Agency also had concerns regarding the effectiveness of Nidlegy because of the design and conduct of the main study. These included uncertainties about the main measure of effectiveness in the main study, since it did not consider patients who were given Nidlegy but did not eventually undergo surgery or who still had signs of cancer after treatment.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not fully addressed its concerns and the benefit of Nidlegy could not be established.

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 they were unlikely to be able to provide the data required to address the Agency's concerns regarding the quality and effectiveness of the medicine within the remaining time available for the procedure.

Does this withdrawal affect patients in clinical trials?

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

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