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Withdrawal of application for the marketing authorisation of Sevsury (*surufatinib*)

Hutchmed Europe B.V. withdrew its application for a marketing authorisation of Sevsury for the treatment of progressive neuroendocrine tumours.

The company withdrew the application on 1 August 2022.

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

Sevsury was developed as a medicine to treat adults with progressive neuroendocrine tumours, a cancer which forms from cells that release hormones. These tumours can develop anywhere in the body, but most occur in the digestive tract or organs like the pancreas or lungs. This medicine was intended to be used in patients whose cancer is considered to grow at either a slow (low grade) or intermediate (intermediate grade) rate and is metastatic (has spread to other parts of the body) or cannot be surgically removed.

Sevsury contains the active substance surufatinib and was to be available as capsules.

How does Sevsury work?

The active substance in Sevsury, surufatinib, blocks the effect of certain proteins called growth factors. Growth factors can be found in certain cancer cells, where they are involved in activating processes that include cell division and the growth of new blood vessels that supply the cancer cells. By blocking the effect of these growth factors, the medicine was expected to slow down the growth and spread of the cancer. Surufatinib also blocks a receptor (target) found in certain cancer cells, called colony-stimulating factor 1 receptor (CSF1R), which helps the cancer cells evade the immune system (the body's natural defences). By blocking CSF1R, the medicine was expected to help the immune system to detect and destroy cancer cells.

What did the company present to support its application?

The company provided results from two main studies which compared the effect of the medicine against placebo (a dummy treatment). The first study was conducted in 172 patients with pancreatic neuroendocrine tumours (cancer of the hormone-producing cells in the pancreas) and the second study was conducted in 198 patients with extra-pancreatic neuroendocrine tumours (cancer of hormone-

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producing cells that are not located in the pancreas). The main measure of effectiveness was how long patients lived without their disease getting worse.

How far into the evaluation was the application when it was withdrawn?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 Sevsury could not have been authorised.

The Agency's concerns were about the effectiveness of the medicine, based on important uncertainties regarding the design and conduct of the main studies. These included the methods used to evaluate the main measure of effectiveness, uncertainties regarding the clinical characteristics of patients who were included within the main studies and compliance with good clinical practice. Adding to these concerns, the results of the main studies were not robust enough to show that Sevsury was effective at treating patients with progressive neuroendocrine tumours. The Agency also had concerns regarding the documentation describing the manufacturing process, leading to uncertainties regarding the quality of the medicine.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Sevsury 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 was not able to satisfactorily address the Agency's concerns, namely those regarding the design and conduct of the main studies, including compliance with good clinical practice, and the benefit-risk profile of the medicine within a European population.

Does this withdrawal affect patients in clinical trials?

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

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