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Withdrawal of application for the marketing authorisation of Jesduvroq (daprodustat)

GlaxoSmithKline Trading Services Limited withdrew its application for a marketing authorisation of Jesduvroq for the treatment of adult patients with symptoms of anaemia caused by chronic kidney disease.

The company withdrew the application on 12 July 2023.

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

Jesduvroq was developed as a medicine to treat the symptoms of anaemia (low red blood cell counts) caused by chronic kidney disease (long-term, progressive decrease in the ability of the kidneys to work properly).

It was intended for adult patients on dialysis (a technique for removing unwanted substances and excess fluid from the blood when the kidneys do not work well enough) as well as patients not on dialysis.

Jesduvroq contains the active substance daprodustat and was to be available as tablets to be taken by mouth.

How does Jesduvroq work?

Patients with chronic kidney disease may not produce enough erythropoietin, a hormone that stimulates the production of red blood cells. The active substance in Jesduvroq, daprodustat, acts on an enzyme called hypoxia-inducible factor prolyl hydroxylase (HIF-PH). This stimulates the natural response that normally occurs when oxygen levels are low, including the production of erythropoietin and red blood cells, thereby reducing the symptoms of anaemia.

What did the company present to support its application?

The company presented the results of three main studies involving over 3,500 patients with anaemia caused by chronic kidney disease who were on dialysis, and two main studies involving nearly 4,500 patients who were not on dialysis. The studies compared Jesduvroq with recombinant human

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erythropoietin, epoetin alfa and darbepoetin alfa (other medicines for treating anaemia) or placebo (a dummy treatment) and looked at the effect of Jesduvroq on increasing or maintaining blood levels of haemoglobin (the protein in red blood cells that carries oxygen around the body) within a target range of 10-11 g/dl (in the studies comparing Jesduvroq to other medicines) or 11-12 g/dl (in the study comparing Jesduvroq with placebo).

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the European Medicines Agency had recommended approving the marketing authorisation. The company withdrew the application before the European Commission had issued a decision on the Agency's recommendation.

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 recommended granting a marketing authorisation for Jesduvroq to treat the symptoms of anaemia caused by chronic kidney disease in adult patients who are on dialysis.

The Agency did not recommend authorising Jesduvroq for patients who are not on dialysis as there were insufficient data to establish its safety in these patients.

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 its decision was based on the recommendation that Jesduvroq be authorised for use only in adults on dialysis and the resulting implications for the company's strategy.

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 compassionate use programmes using Jesduvroq.

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