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Approval of the marketing authorisation for Rezurock (belumosudil)

Re-examination leads to recommendation to approve

After re-examining its initial opinion, the European Medicines Agency has recommended a conditional marketing authorisation for the medicine Rezurock for the treatment of chronic graft-versus-host disease (a long-term condition in which donor cells from a bone marrow or stem cell transplant attack the body's organs).

The Agency had initially refused the application on 16 October 2025. After concluding the re-examination on 29 January 2026, the Agency recommended the granting of a conditional marketing authorisation.

The company that applied for authorisation is Sanofi Winthrop Industrie.

What is Rezurock and what is it to be used for?

Rezurock is a medicine for treating chronic graft-versus-host disease in adults and in adolescents from 12 years of age weighing at least 40 kg. It is used when all other available treatments have not worked well enough or are not suitable.

Rezurock contains the active substance belumosudil and is to be available as tablets.

Rezurock was designated an 'orphan medicine' (a medicine used in rare diseases) on 17 October 2019 for the treatment of graft-versus-host disease. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu3192205

How does Rezurock work?

The active substance in Rezurock, belumosudil, stops the action of ROCK2, a protein involved in the immune reactions that take place in chronic graft-versus-host disease. By blocking the action of this protein, Rezurock is expected to help treat the condition and protect the body's organs from being attacked by donor cells.

What did the company present to support its application?

The company presented results from a main study involving 156 patients with chronic graft-versus-host disease who had tried at least two other treatments. Patients were also allowed to take other

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treatments, and Rezurock was not compared with any other treatment. This study looked at the proportion of patients taking Rezurock 200 mg once a day who had either a complete response (meaning all symptoms in all affected organs resolved) or a partial response (meaning at least one organ improved and no other organ worsened or was affected).

During the assessment, the company informed the Agency of results from an ongoing study of Rezurock used as a first treatment in patients with chronic graft-versus-host disease.

What were the main reasons for initially refusing the marketing authorisation?

The Agency initially noted that it was difficult to quantify the effect of Rezurock in patients with chronic graft-versus-host disease who had tried other treatments. The main study did not compare Rezurock with any other treatment, and patients also received other medicines.

The Agency also noted that the study in patients with chronic graft-versus-host disease who received Rezurock as a first treatment did not show that it had any beneficial effects. The study had to be stopped early because of the lack of evidence of a benefit, and the results cast further doubt about the use of Rezurock in patients who have had previous treatments.

Given the urgent need for new treatments for patients who have no suitable treatment options, the Agency considered a conditional marketing authorisation, which would have allowed the medicine to be authorised provided the company could submit further data within a short period of time. However, the company is not expected to provide further data on the effectiveness of Rezurock before 2030.

Therefore, the Agency's opinion was that the benefits of Rezurock did not outweigh its risks, and it recommended refusing marketing authorisation.

What happened during the re-examination?

During the re-examination, the Agency reconsidered the available data and took advice from a group of external clinicians with expertise in managing patients with chronic graft-versus-host disease.

What were the conclusions of the re-examination?

As with the initial evaluation, the Agency considered the urgent need for new treatments for patients with chronic graft-versus-host disease when other treatments have failed or are not suitable.

The Agency agreed that there was evidence of Rezurock's beneficial effect in patients, although the size of the benefit is uncertain. The Agency noted that over a 6-month period, 73% of patients who took 200 mg once daily had responded to treatment (with 44% still showing a response at 6 months). It was unlikely that this result could be achieved with only the other medicines they were taking.

The Agency was also reassured that the planned study can collect the necessary data to confirm the beneficial effect of Rezurock within a reasonable period of time. The company was requested to provide regular updates on how the study is progressing.

The Agency therefore concluded that the benefits of Rezurock outweigh its risks and recommended granting it a conditional marketing authorisation.

For a conditional marketing authorisation, a medicine can be authorised with less comprehensive data than are normally required if it fulfils an unmet medical need. The Agency considers that there is sufficient evidence on the benefits and risks of Rezurock to allow the medicine to be available while awaiting further data. Every year, the Agency will review any new information that becomes available.