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Refusal of the marketing authorisation for Kinselby (resminostat)

The European Medicines Agency has recommended the refusal of marketing authorisation for Kinselby, a medicine intended for the treatment of mycosis fungoides and Sézary syndrome, two rare cancers of white blood cells that affect the skin.

The Agency issued its opinion on 22 May 2025. The company that applied for authorisation, 4SC AG, may ask for re-examination of the opinion within 15 days of receiving the opinion.

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

Kinselby is a medicine developed for treating advanced stages of mycosis fungoides and Sézary syndrome, two cancers that affect white blood cells called T-cells and cause lesions and growths on the skin. It was intended for people whose condition was stable after treatment with systemic medicines (medicines that work throughout the body) or skin radiation.

Kinselby contains the active substance resminostat and was to be available as tablets.

How does Kinselby work?

The active substance in Kinselby, resminostat, is a histone deacetylase (HDAC) inhibitor. This means that it blocks the activity of histone deacetylases, enzymes that can turn genes on and off and play a role in the development of cancer. By blocking the activity of these enzymes, the medicine was expected to help turn on genes that suppress the growth of cancer cells while helping to turn off those that promote it.

What did the company present to support its application?

The company presented results from a main study of 201 patients with advanced stages of mycosis fungoides or Sézary syndrome that was under control with other treatments. Patients in the study took either Kinselby or placebo (a dummy treatment) and the main measure of effectiveness was how long the patients lived without their disease getting worse.

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What were the main reasons for refusing the marketing authorisation?

The Agency's human medicines committee (CHMP) noted that the main study did not provide enough evidence that Kinselby is effective in patients with stable mycosis fungoides or Sézary syndrome. There were some problems with the way the study was carried out, which meant that it was not possible to rely on data showing how long patients lived without their disease getting worse. In addition, the study did not show that Kinselby was effective in other measures such as improving overall survival (how long they lived overall).

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

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

The company informed the Agency that there are no ongoing clinical trials or compassionate use programmes with Kinselby.