24 July 2026
EMA/167339/2026
EMEA/H/C/006317

Update as of 4 August 2026:

The company for Qezzaqar has requested a re-examination of EMA's opinion issued on 23 July 2026. Upon receipt of the grounds of this request, the Agency will re-examine its opinion and issue a final recommendation.

Refusal of the marketing authorisation for Qezzaqar (catequentinib)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Qezzaqar, a medicine intended for the treatment of leiomyosarcoma and synovial sarcoma, two types of cancer of the soft tissue.

The Agency issued its opinion on 23 July 2026. The company that applied for authorisation, CATS Consultants GmbH, may ask for re-examination of the opinion within 15 days of receiving the opinion.

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

Qezzaqar was developed as a cancer medicine for the treatment of two types of soft tissue sarcoma (a type of cancer that affects the soft, supportive tissues of the body):

- leiomyosarcoma, a type of soft tissue sarcoma that affects the smooth muscle. It was to be used in adults whose cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), and in whom two previous therapies have failed (including anthracycline-containing chemotherapy, unless they could not have it);
- synovial sarcoma, another type of soft tissue sarcoma that most commonly grows around the knee or ankle joints and in other joints such as the hip or shoulder. Qezzaqar was to be used in adults whose cancer is unresectable or metastatic, and in whom one previous therapy has failed (including anthracycline-containing chemotherapy, unless they could not have it).

Qezzaqar contains the active substance catequentinib and was to be available as capsules to be taken by mouth.

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Qezzaqar was designated an 'orphan medicine' (a medicine used in rare diseases) on 22 February 2018 for the treatment of soft tissue sarcoma. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu-3-18-1972.

How does Qezzaqar work?

The active substance in Qezzaqar, catequentinib, belongs to a class of cancer medicines called tyrosine kinase inhibitors and blocks several receptors (targets) that are important for the development of new blood vessels that help the cancer to grow, including VEGF receptors. By blocking these receptors, the medicine was expected to reduce the supply of blood to the cancer and thereby slow the cancer's growth and spread.

What did the company present to support its application?

The company presented data from a main study which involved patients with different types of cancer. Of these patients, 79 had metastatic or advanced synovial sarcoma and received either Qezzaqar or dacarbazine, a chemotherapy treatment, while 111 patients had metastatic or advanced leiomyosarcoma and received either Qezzaqar or placebo (a dummy treatment). In both groups, the main measure of effectiveness was how long patients lived without their disease getting worse (progression-free survival).

What were the main reasons for refusing the marketing authorisation?

The European Medicines Agency concluded that in both conditions the benefits observed in terms of progression-free survival were very limited and not supported by other measures of effectiveness such as objective responses to treatment (shrinkage of the tumour or no detectable sign of cancer after treatment) or overall survival (how long people lived overall). In addition, there were significant uncertainties about the robustness of the data. In particular, due to the small size of the control groups (patients given placebo or a comparator medicine), differences between participants at the start of the study may have had an impact on the results. In terms of safety, in line with other VEGF inhibitors, Qezzaqar is associated with important side effects, including some that were serious and led to death.

Therefore, the Agency's opinion was that the benefits of Qezzaqar 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 consequences for patients in clinical trials or in compassionate use programmes with Qezzaqar for these two indications.

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