26 June 2026
EMA/127401/2026
EMEA/H/C/006563

Refusal of the marketing authorisation for Tacquell (autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo-expanded)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Tacquell, a medicine intended for the treatment of advanced melanoma (a skin cancer that has spread elsewhere in the body).

The Agency issued its opinion on 25 June 2026. The organisation that applied for authorisation, the Netherlands Cancer Institute, may ask for re-examination of the opinion within 15 days of receiving the opinion.

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

Tacquell was developed as a medicine to treat advanced (stage IIIC to IV) melanoma that is unresectable (cannot be removed by surgery). It was to be used in adults who had already received treatment with a type of cancer medicine that blocks a receptor (target) called PD-1.

Tacquell is an advanced therapy medicinal product (ATMP) that is based on the patient's own cells. It contains autologous melanoma-derived tumour infiltrating lymphocytes (TILs) as the active substance. These are white blood cells that are collected from a metastasis (cancer that has spread) removed from the patient. The medicine was to be available as a cell dispersion to be given as a single infusion (drip) into a vein.

Before receiving Tacquell, the patients would be given chemotherapy (other cancer medicines) to clear their own lymphocytes (a type of white blood cells). After receiving Tacquell, they would be given a medicine called interleukin-2 to stimulate the growth and activity of the TILs.

How does Tacquell work?

Tumour infiltrating lymphocytes are white blood cells made by the immune system (the body's natural defences) that recognise and kill cancer cells. After being collected from the patient, the cells are grown in the lab to increase their numbers. When given back to the patient, they were expected to help the immune system kill the cancer cells.

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What did the medicine developer present to support its application?

The applicant presented the results of a main study involving 168 adults with unresectable advanced melanoma who received either Tacquell or another cancer medicine called ipilimumab. The main measure of effectiveness was how long patients lived without their cancer getting worse.

What were the main reasons for refusing the marketing authorisation?

Overall, the Agency considered that the main efficacy and safety data submitted by the applicant were not reliable and that the benefits of Tacquell have not been demonstrated.

In particular, a good clinical practice (GCP) inspection found critical problems with GCP compliance in the main study, which compromised the reliability and integrity of the clinical data and made it difficult to trace or reproduce the data. The Agency also had multiple concerns about the study design and how the data had been analysed, limiting the ability to interpret the main study results. In addition, the Agency could not fully assess the safety of Tacquell and its treatment regimen because the data were incomplete.

In terms of quality, there were concerns about the quality control strategy for the commercial product and for a critical raw material used during the manufacturing process. There were also concerns about the comparability between batches produced across different sites and between clinical and commercial batches. In addition, documentation demonstrating compliance with good manufacturing practice (GMP) was incomplete for the sites responsible for the manufacture and quality control of the commercial active substance and finished product.

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

Does this refusal affect patients currently involved in hospital exemption programmes?

Patients in a hospital exemption programme should speak with their doctor for more information about their treatment.