swissmedic

Summary report on authorisation dated 27 July 2026

ZYNYZ® (active substance: retifanlimab)

Indication extension in Switzerland: 24 April 2026

Concentrate for solution for infusion for the treatment of adult patients with metastatic or inoperable, locally recurrent squamous cell carcinoma of the anal canal in combination with carboplatin and paclitaxel.

About the medicinal product

ZYNYZ contains the active substance retifanlimab.

ZYNYZ was first authorised by Swissmedic on 24 June 2025 for the treatment of adults with Merkel cell carcinoma (MCC; a type of skin cancer) that is not amenable to surgery or radiation therapy.

The current indication extension means that ZYNYZ can now also be used in combination with carboplatin and paclitaxel for the treatment of adults with squamous cell carcinoma of the anal canal (SCAC). ZYNYZ is used for this indication when the cancer has spread to other parts of the body (metastasised) or has recurred and cannot be treated with surgery.

SCAC is a rare type of cancer that affects the final section of the bowel.

Since this is a rare and life-threatening or chronically debilitating disease, the medicinal product ZYNYZ has been authorised as an orphan drug. The term "orphan drug" refers to medicinal products used to treat patients with rare diseases.

Mode of action

The active substance in ZYNYZ is a monoclonal antibody (immunologically active protein) that binds to a specific protein known as PD-1 (programmed cell death receptor-1) and thereby prevents it from binding to the PD-ligand (programmed cell death-ligand). As a result, the tumour-mediated inhibition of T-cell activity is reversed, leading to an enhanced immune response to the tumour and potentially delaying or stopping tumour growth.

ZYNYZ is used together with the chemotherapy medicines carboplatin and paclitaxel. The chemotherapy attacks the cancer cells directly, while ZYNYZ supports the immune system. This combination is intended to slow the progression of the disease.

Administration

ZYNYZ is a prescription-only medicine.

ZYNYZ is administered as an infusion into a vein. The treatment may only be initiated and supervised by a doctor experienced in the treatment of cancer.

ZYNYZ is available as a concentrate for solution for infusion. A vial contains 500 mg of retifanlimab.

ZYNYZ is administered to adults every 4 weeks as an infusion over 30 minutes. At the start of treatment, ZYNYZ is given together with carboplatin and paclitaxel. This combination is administered for 6 treatment cycles, after which ZYNYZ is continued on its own.

The treatment is continued until the disease worsens or severe side effects occur, subject to a maximum period of a year.

Efficacy

The efficacy of ZYNYZ was investigated in a study (POD1UM-303/InterAACT-2) with adults suffering from metastatic or inoperable SCAC who had not previously received any chemotherapy for this advanced disease. A total of 308 patients took part in the study. All participants received chemotherapy with carboplatin and paclitaxel. One group also received ZYNYZ and the other group placebo (dummy drug).

The study showed that the time to progression of the disease (progression-free survival) was significantly prolonged in patients who received ZYNYZ in addition to the chemotherapy. The patients treated with ZYNYZ lived longer, on average, than those in the comparator group.

Precautions, undesirable effects, & risks

ZYNYZ must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects in combination with carboplatin and paclitaxel (affecting more than 1 in 10 users) include decreased white blood cell count (neutrophils), diarrhoea, skin reactions such as itching or rash, decreased lymphocytes, changes in thyroid function and elevated liver enzymes (elevated transaminases).

In addition, immune-mediated inflammatory reactions can occur in various organs, which can also manifest after discontinuation of treatment

Patients must therefore be monitored carefully during and after treatment.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Limited treatment options are currently available for patients with metastatic or inoperable SCAC. Since the disease continues to progress in many patients despite chemotherapy, there is a need for additional treatments that can improve the existing standard treatment.

The study showed that the combination of ZYNYZ with carboplatin and paclitaxel can

delay the disease for longer than chemotherapy on its own.

Taking all the risks and precautions into account, and based on the available data, the benefits of ZYNYZ outweigh the risks. Swissmedic has therefore authorised the indication extension in Switzerland for the medicinal product ZYNYZ, containing the active substance retifanlimab, for the first-line treatment of adult patients with metastatic or inoperable, locally recurrent SCAC.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals ZYNYZ®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.