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Opdualag (*nivolumab / relatlimab*)

An overview of Opdualag and why it is authorised in the EU

What is Opdualag and what is it used for?

Opdualag is a medicine used as a first-line treatment for melanoma (a type of skin cancer) that has spread or cannot be surgically removed. It is used for patients from 12 years of age whose cancer cells produce a low level (<1%) of a protein called PD-L1.

Opdualag contains the active substances nivolumab and relatlimab.

How is Opdualag used?

Before starting treatment with Opdualag, the patient should have a test to show that their cancer cells produce low levels of PD-L1 (<1%).

The medicine is given as an infusion into a vein over 30 minutes once every 4 weeks. Treatment should continue for as long as the patient benefits from it or does not have intolerable side effects. If certain side effects occur, the doctor may delay doses or stop treatment altogether.

For more information about using Opdualag, see the package leaflet or contact your doctor or pharmacist.

How does Opdualag work?

The active substances in Opdualag, nivolumab and relatlimab, are monoclonal antibodies, proteins designed to attach to specific receptors (targets).

Nivolumab attaches to a receptor called PD-1 on cells of the immune system called T cells. Cancer cells can produce proteins (PD-L1 and PD-L2) on their surface that attach to the PD-1 receptor and switch off the activity of the T cells, preventing them from attacking the cancer. By attaching to the receptor, nivolumab prevents PD-L1 and PD-L2 from switching off the T cells, thereby increasing the ability of the immune system to kill cancer cells.

Relatlimab attaches to and blocks another receptor known as LAG-3. LAG-3 is involved in reducing the immune response By blocking LAG-3, relatlimab causes the activation of more T cells, thereby increasing the ability of the immune system to attack and kill the cancer cells.

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Using nivolumab and relatlimab together is more effective at killing the cancer cells than using them alone.

What benefits of Opdualag have been shown in studies?

A main study involving 714 patients with previously untreated advanced melanoma showed that Opdualag was effective at slowing the worsening of the disease in those patients whose cancer produced a low level amount of PD-L1.

Patients with low levels of PD-L1 (<1%) who had Opdualag treatment lived for 6.7 months without their disease getting worse. This compares with 3 months for patients having treatment with nivolumab alone.

What are the risks associated with Opdualag?

The most common side effects with Opdualag (which may affect more than 1 in 10 people) are tiredness, pain in muscles and bones, rash, joint pain, diarrhoea, itching, headache, nausea, cough reduced appetite, hypothyroidism (an underactive thyroid gland), abdominal pain, vitiligo (white patches on the skin), fever, constipation, urinary tract infection (infection of the parts of the body that collect and pass out urine), dyspnoea (difficulty breathing), and vomiting.

The most common serious side effects are adrenal insufficiency (where the adrenal glands on top of the kidneys do not make enough of certain hormones), anaemia (low levels of red blood cells), back pain, colitis (inflammation in the large bowel), diarrhoea, myocarditis (inflammation of heart muscle), pneumonia (infection of the lungs) and urinary tract infection.

For the full list of side effects and restrictions, see the package leaflet.

Why is Opdualag authorised in the EU?

The main study showed that Opdualag was effective at slowing the worsening of the disease in those patients whose cancer produces a small amount of PD-L1 (<1%). Although there are more side effects with Opdualag than with nivolumab alone, the benefits in delaying worsening of the disease outweigh the risks in these patients. The European Medicines Agency therefore recommended authorising the medicine in the EU.

What measures are being taken to ensure the safe and effective use of Opdualag?

The company will provide a patient card with information on the risks of the medicine as well as instructions on when to contact their doctor if they have symptoms of immune-related side effects.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Opdualag have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Opdualag are continuously monitored. Suspected side effects reported with Opdualag are carefully evaluated and any necessary action taken to protect patients.

Other information about Opdualag

Opdualag received a marketing authorisation valid throughout the EU on 15 September 2022.

Further information on Opdualag can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/opdualag

This overview was last updated in 09-2022.