swissmedic

Summary report on authorisation dated 4 September 2026

Opdualag® (active substances: nivolumab, relatlimab)

Indication extension in Switzerland: 20 April 2026

Concentrate for solution for infusion for the first-line treatment of adults with unresectable or metastatic melanoma

About the medicinal product

The medicinal product Opdualag contains two monoclonal antibodies (immunologically active proteins): nivolumab and relatlimab.

Opdualag is used for the first-line treatment of adults with melanoma that cannot be removed by surgery (unresectable) or which has spread (metastatic).

Swissmedic first authorised Opdualag on 23 December 2022 for the first-line treatment of adults with unresectable or metastatic melanoma with PD-L1 expression below 1%.

This indication extension means that Opdualag can be used regardless of PD-L1 expression.

Mode of action

Opdualag contains a fixed combination of the active substances nivolumab (what is known as a PD-1 inhibitor) and relatlimab (a LAG-3 inhibitor).

PD-1 (programmed cell death protein 1) is a receptor (target site) on immune cells. These immune cells form part of the body's natural defences. When the receptor is activated by a PD-L1 (PD-ligand 1) – a protein – the body's immune response is reduced.

Certain cancer cells can form a PD-L1 surface protein of this type, which then reduces the body's immune response to the cancer cells. Preventing the PD-L1 from binding to the PD-1 receptor by means of a PD-1 inhibitor such as nivolumab therefore increases the activity of the body's own defence system towards the tumour tissue.

Additionally, relatlimab inhibits LAG-3 (lymphocyte-activation gene 3), a further inhibitory receptor found on immune cells. Simultaneously blockading PD-1 and LAG-3 strengthens the body's own immune response to cancer cells.

Administration

Opdualag, containing the active substances nivolumab and relatlimab, is a prescription-only medicine.

Opdualag is available as a concentrate used to make an infusion; the 20 mL vial contains 240 mg nivolumab and 80 mg relatlimab.

The recommended dosage of Opdualag (480 mg nivolumab and 160 mg relatlimab) is administered every 4 weeks as a 30-minute infusion into a vein.

Efficacy

The efficacy of Opdualag in the indication extension was evaluated using updated data from the RELATIVITY-047 study. This study compared Opdualag (nivolumab in combination with relatlimab) with nivolumab monotherapy in adults with previously untreated unresectable or metastatic melanoma. The initial authorisation of Opdualag in Switzerland was based on this study.

The updated evaluation showed an advantage for Opdualag compared to nivolumab monotherapy in all participants (overall population), regardless of PD-L1 expression. Median[1] progression-free survival (PFS)[2] was 10.2 months for Opdualag combination therapy compared to 4.6 months for nivolumab monotherapy. Overall survival was also higher: Median[3] overall survival (OS) was 53.3 months for Opdualag compared to 33.2 months for nivolumab monotherapy. Overall survival was consistent between patients with PD-L1 expression below 1% and patients with PD-L1 expression of at least 1%.

Precautions, undesirable effects, & risks

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

The safety profile of Opdualag corresponded to current findings. No new safety signals and no additional deaths attributable to toxicity of the trial medication were identified in the updated study data.

The most commonly observed undesirable effects were fatigue, musculoskeletal pain, rash, pruritus, joint pain, nausea and diarrhoea. Immune-mediated undesirable effects may affect various organ systems and occur even after treatment has been discontinued. Patients should 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

The updated data from the RELATIVITY-047 study show that Opdualag offers benefits

[1] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

[2] PFS: Progression-free survival. Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[3] Overall survival (OS): Overall survival refers to the period between the start of treatment and the death of the patient.

over nivolumab monotherapy in terms of progression-free survival in adults with previously untreated unresectable or metastatic melanoma. Furthermore, the updated overall survival data support a positive risk/benefit profile in the overall population.

Taking all the risks and precautions into account, and based on the available data, the benefits of Opdualag in the indication extension outweigh the risks. Swissmedic has therefore extended the indication of Opdualag such that the medicinal product is authorised for the first-line treatment of adults with unresectable or metastatic melanoma regardless of PD-L1 expression.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Opdualag®

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.