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Imjudo® (active substance: tremelimumab)

First authorisation in Switzerland: 13 September 2023

Medicinal product (concentrate for solution for infusion) given in combination with durvalumab for the first-line treatment of patients with unresectable hepatocellular carcinoma (uHCC)

About the medicinal product

The medicinal product Imjudo containing the active substance tremelimumab is used in combination with the active substance durvalumab[1] for the treatment of patients with unresectable hepatocellular carcinoma (uHCC). The patients will not have received any prior systemic treatment[2].

Hepatocellular carcinomas are aggressive tumours that often occur in connection with chronic liver disease and liver cirrhosis. As a rule, they are only diagnosed late in the course of the liver disease.

Since uHCC is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

The active substance in Imjudo, tremelimumab, is a monoclonal antibody.

Monoclonal antibodies are proteins that can bind specifically to other proteins.

Tremelimumab binds to what is known as the "CTLA-4 antigen", a protein that controls the activity of T-cells. T-cells are part of the immune system (the body's own defence system). Tremelimumab's ability to bind to CTLA-4 inhibits the activity of CTLA-4. That in turn increases the number and activity of T-cells, which are able to kill off cancer cells.

Based on another mechanism, durvalumab also has the effect of increasing the activity of the body's defence system against the tumour, which further strengthens the anti-tumour immune response to tremelimumab and slows down the spread of the cancer.

[1] Durvalumab is an active substance that has already been authorised. A monoclonal antibody belonging to the group of immune checkpoint inhibitors, it is used to treat malignant tumours.

[2] Systemic therapy: in contrast to local therapy (treatment at the site of the disorder), systemic therapy involves treatment of the entire body to eliminate a disorder.

Administration

Imjudo, containing the active substance tremelimumab, is a prescription-only medicine.

It is given intravenously, i.e. as an infusion into the veins, for the duration of one hour.

The recommended dose of Imjudo for patients weighing at least 30 kg is 300 mg, in combination with 1500 mg durvalumab in cycle 1 on the first day, followed by durvalumab (1500 mg) given as a single agent (monotherapy) every four weeks.

For patients weighing less than 30 kg, the recommended dose is 4 mg Imjudo per kg bodyweight and 20 mg durvalumab per kg bodyweight in cycle 1 on the first day followed by durvalumab (1500 mg) given as monotherapy every four weeks until the bodyweight reaches 30 kg.

Treatment should continue until such time as the disease progresses or until side effects become too severe.

Efficacy

The efficacy of Imjudo was investigated in a study with 1324 patients (the HIMALAYA study). The patients were divided into 4 groups: 2 different Imjudo dosages (300 mg or 75 mg) were given in combination with durvalumab and compared with treatment solely with durvalumab or sorafenib (authorised treatment option).

The study's primary endpoint was the overall survival (OS)[3] of the patients given 300 mg Imjudo in combination with durvalumab.

The treatment with 300 mg Imjudo in combination with durvalumab showed a statistically significant improvement in OS compared with treatment with sorafenib. Those patients who were treated with Imjudo in combination with durvalumab had a median[4] overall survival of 16.4 months. By comparison, those patients who were treated with sorafenib lived for a further 13.8 months (median figure).

Precautions, undesirable effects, & risks

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

The most common adverse effects (those affecting more than 1 in 10 users) are diarrhoea, skin rash, itching, cough, fever, abdominal pain, reduced thyroid gland activity, and increased levels of aspartate aminotransferase and alanine aminotransferase[5].

Common severe adverse effects (affecting up to 1 in 10 users) are inflammations of the large intestine and pneumonia.

Inhibition of the body's defence system may also give rise to immune-mediated adverse effects.

All precautions, risks, and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

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

[4] 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 smaller than the median, the other half are always greater.

[5] Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are enzymes produced mainly in the liver. Elevated levels of activity of these enzymes in the blood may indicate liver-related diseases.

Why the medicinal product has been authorised

Hepatocellular carcinoma (HCC) is the fifth commonest type of cancer globally and the second most frequent cause of cancer-related deaths in men.

Although therapies already exist for the treatment of HCC, the disease is incurable and there is a great medical need for safe and effective treatment options.

The HIMALAYA study that has now been carried out showed that Imjudo in combination with durvalumab can increase the survival time of patients compared to treatment with sorafenib. The side effects of Imjudo given in combination with durvalumab may be serious.

Taking all the risks and precautions into account, and based on the available data, the benefits of Imjudo in combination with durvalumab outweigh the risks. Swissmedic has therefore authorised the medicinal product Imjudo containing the active substance tremelimumab for the indication requested, unresectable hepatocellular carcinoma (uHCC), for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Imjudo®

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 Public Summary SwissPAR.

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