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Imjudo (*tremelimumab*)

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

What is Imjudo and what is it used for?

Imjudo is a cancer medicine. It is used to treat:

- hepatocellular carcinoma (a type of liver cancer) in adult patients who have not been treated before and whose disease is advanced or unresectable (cannot be removed by surgery). It is used in combination with durvalumab, another cancer medicine;
- non-small cell lung cancer (NSCLC) that has metastasised (spread to other parts of the body) in adult patients who have not been treated before. It is given together with durvalumab and platinum-based chemotherapy and is used when the cancer has shown no mutations (changes) in the so-called *EGFR* and *ALK* genes.

Imjudo contains the active substance tremelimumab.

How is Imjudo used?

Imjudo can only be obtained with a prescription and treatment must be started and supervised by a doctor with experience in treating cancer.

Imjudo is given as an infusion (drip) into a vein which lasts about an hour.
For the treatment of hepatocellular carcinoma, Imjudo is given once, in combination with durvalumab. After that, treatment with durvalumab is given every four weeks on its own until the disease gets worse or side effects become unacceptable.
For the treatment of NSCLC, Imjudo is given in combination with durvalumab and chemotherapy until the disease gets worse or side effects become unacceptable, for up to a maximum of 5 doses.

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

How does Imjudo work?

The active substance in Imjudo, tremelimumab, is a monoclonal antibody (a type of protein). It is designed to attach to and block CTLA-4, a protein that controls the activity of T cells which are part of the immune system (the body's natural defences). By blocking CTLA-4, the medicine increases the

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number and activity of T cells, which can then kill cancer cells. This is expected to slow down the spread of the cancer.

What benefits of Imjudo have been shown in studies?

In a main study in patients with advanced hepatocellular carcinoma who had not been treated before and whose cancer cannot be removed by surgery, Imjudo in combination with durvalumab increased the time patients lived overall compared with standard treatment (sorafenib): patients who received Imjudo plus durvalumab (393 patients) lived on average 16.4 months compared with 13.8 months for those who received sorafenib (389 patients). In about 20% of patients who received Imjudo and durvalumab the tumour shrank or disappeared, and this response lasted about 22 months on average. About 5% of patients who received sorafenib had a response to treatment and their response lasted on average 18 months.

In a main study in patients with metastatic NSCLC, 338 patients given Imjudo in combination with durvalumab and chemotherapy lived on average for 14 months, compared with 12 months for 337 patients given only chemotherapy. They also lived longer without their disease getting worse: around 6 months on average, compared with 5 months for patients who only received chemotherapy.

What are the risks associated with Imjudo?

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

The most common side effects with Imjudo in combination with durvalumab (which may affect more than 1 in 10 people) include rash, pruritus (itching), diarrhoea, abdominal (belly) pain, increased levels of liver enzymes, fever, hypothyroidism (an underactive thyroid gland), cough and peripheral oedema (swelling especially of the ankles and feet).

The most common serious side effects (which may affect up to 1 in 10 people) include colitis (inflammation in the large bowel), diarrhoea and pneumonia (infection of the lungs).

The most common side effects with Imjudo in combination with durvalumab and platinum-based chemotherapy (which may affect more than 1 in 10 people) include anaemia (low levels of red blood cells), nausea (feeling sick), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), tiredness, decreased appetite, rash, thrombocytopenia (low levels of blood platelets), diarrhoea, leukopenia (low levels of white blood cells), constipation, vomiting, increased levels of liver enzymes, fever, upper respiratory tract (nose and throat) infections, pneumonia, hypothyroidism, joint pain, cough and pruritus.

The most common serious side effects (which may affect up to 1 in 10 people) include pneumonia, anaemia, thrombocytopenia, colitis, diarrhoea, fever and neutropenia with fever.

Imjudo is commonly associated with side effects related to the activity of the immune system on body organs, such as immune-mediated colitis, hepatitis (inflammation of the liver) and hypothyroidism.

Why is Imjudo authorised in the EU?

The European Medicines Agency decided that Imjudo’s benefits are greater than its risks and it can be authorised for use in the EU.

Imjudo, given in combination with durvalumab to treat hepatocellular carcinoma or with durvalumab and chemotherapy to treat metastatic NSCLC, can increase the time patients live compared to treatment with standard therapy. When treating hepatocellular carcinoma, the side effects with Imjudo given in combination with durvalumab can be serious, but they are not more serious than those of the

standard therapy. For the treatment of NSCLC, the addition of Imjudo and durvalumab to chemotherapy, in particular concerning immune-related side effects, can be serious, and warrant precaution when treating frail or elderly patients.

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

The company that markets Imjudo must provide healthcare professionals prescribing the medicine with educational materials on the potential risk of immune-related side effects. Patients will also receive an alert card from their doctor summarising key safety information for the medicine.

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

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

Other information about Imjudo

Imjudo received a marketing authorisation valid throughout the EU on 20 February 2023.

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

This overview was last updated in 07-2023.