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Imfinzi (*durvalumab*)

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

What is Imfinzi and what is it used for?

Imfinzi is a medicine used to treat lung cancer. It is for use in adults with:

- non-small cell lung cancer (NSCLC) that is locally advanced (meaning it has spread into tissues around the lungs, but not to other parts of the body) and cannot be removed by surgery and is not getting worse after radiation treatment and platinum-based chemotherapy (medicines to treat cancer). Imfinzi is used on its own and only when the cancer produces a protein known as PD-L1;
- NSCLC that has metastasised (spread) outside the lungs. Imfinzi is given together with tremelimumab (another cancer medicine) and platinum-based chemotherapy, and is used when the cancer has no mutations (changes) in the so-called *EGFR* and *ALK* genes;
- small cell lung cancer (SCLC) that has spread within the lungs or to other parts of the body (extensive-stage SCLC) and has not been treated previously. Imfinzi is given together with etoposide and either carboplatin or cisplatin (chemotherapy medicines);
- biliary tract cancer (BTC), a cancer of the bile ducts (tubes that carry bile from the liver and gallbladder to the gut). It is used in combination with gemcitabine and cisplatin (other cancer medicines) in patients who have not been treated previously, when the cancer cannot be removed by surgery or has metastasised;
- hepatocellular carcinoma (HCC, a type of liver cancer) in patients who have not been treated before and whose disease is advanced or cannot be removed by surgery. Imfinzi can be used on its own or in combination with tremelimumab.

Imfinzi contains the active substance durvalumab.

How is Imfinzi used?

Imfinzi can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in treating cancer. It is given by infusion (drip) into a vein.

The dose of Imfinzi and how often it is given depends on the type of cancer being treated. Treatment can continue for as long as the patient benefits from it or for up to 1 year for locally advanced NSCLC.

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Treatment may be paused or stopped permanently if the patient gets severe side effects.

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

How does Imfinzi work?

The active substance in Imfinzi, durvalumab, is a monoclonal antibody, a type of protein designed to attach to a protein called PD-L1, which is present on the surface of many cancer cells.

PD-L1 acts to switch off immune cells that would otherwise attack the cancer cells. By attaching to PD-L1 and blocking its effects, Imfinzi increases the ability of the immune system to attack the cancer cells and thereby slows down the progression of the disease.

What benefits of Imfinzi have been shown in studies?

Non-small cell lung cancer

In one main study of 713 patients with locally advanced non-small cell lung cancer, patients given Imfinzi lived on average for around 17 months without their disease getting worse, compared with 6 months for those given placebo (a dummy treatment). Preliminary results also indicated that patients given Imfinzi lived longer overall compared with patients on placebo.

In another main study of patients with metastatic NSCLC, 338 patients given Imfinzi in combination with tremelimumab 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.

Small cell lung cancer

In another main study of 805 patients with extensive-stage small cell lung cancer, patients given Imfinzi together with chemotherapy lived on average for 13 months compared with 10 months for those given chemotherapy alone.

Biliary tract cancer

In a study with 685 patients with advanced biliary tract cancer, patients who received Imfinzi plus gemcitabine and cisplatin lived on average for 12.8 months, compared with 11.5 for those who received placebo plus gemcitabine and cisplatin.

Hepatocellular carcinoma

In a main study involving patients with advanced hepatocellular cancer who had not been treated before, Imfinzi given on its own and in combination with tremelimumab increased the time patients lived overall compared with standard treatment (sorafenib). Patients who received either Imfinzi on its own (389 patients) or together with tremelimumab (393 patients) lived for an average of 16.6 months and 16.4 months, respectively, compared with an average of 13.8 months for those who received sorafenib (389 patients).

In about 17% of patients who received Imfinzi on its own, the tumour shrank or disappeared; this response lasted for about 17 months on average. While in about 20% of patients who received Imfinzi with tremelimumab, the tumour shrank or disappeared, with the response lasting 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.

What are the risks associated with Imfinzi?

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

When Imfinzi is given alone, the most common side effects (which may affect more than 1 in 10 people) include cough, nose and throat infections, fever, diarrhoea, arthralgia (joint pain), abdominal (belly) pain, rash, itching and hypothyroidism (an underactive thyroid gland).

When Imfinzi is given together with chemotherapy, the most common side effects (which may affect more than 1 in 10 people) include leucopenia (low levels of white blood cells, including neutrophils which fight infections), anaemia (low levels of red blood cells), nausea (feeling sick), tiredness, thrombocytopenia (low levels of platelets in the blood), constipation, decreased appetite, abdominal pain, hair loss, vomiting, diarrhoea, fever, rash, itching, increased level of liver enzymes and cough.

When Imfinzi is given with tremelimumab and chemotherapy for non-small cell lung cancer, the most common side effects (which may affect more than 1 in 5 people) include anaemia, nausea, neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), tiredness, rash, thrombocytopenia and diarrhoea.

When Imfinzi is given with tremelimumab for hepatocellular cancer, the most common side effects (which may affect more than 1 in 10 people) include rash, itching, diarrhoea, abdominal pain, increased levels of liver enzymes, fever, hypothyroidism, cough, and peripheral oedema (swelling especially of the ankles and feet); increased levels of lipase may affect up to 1 in 10 people.

Why is Imfinzi authorised in the EU?

Imfinzi was shown to increase the time patients with locally advanced NSCLC lived without their disease getting worse and the time patients with extensive small cell lung cancer, advanced hepatocellular carcinoma or advanced biliary tract cancer lived overall. In combination with tremelimumab, Imfinzi had beneficial effects in patients with NSCLC and in those with hepatocellular carcinoma. The use of Imfinzi in patients with locally advanced NSCLC is restricted to those whose cancer produces PD-L1, since a clear benefit was only shown in this group of patients. Side effects with Imfinzi were considered manageable, and its safety profile acceptable and in line with that of similar medicines.

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

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

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

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

Other information about Imfinzi

Imfinzi received a marketing authorisation valid throughout the EU on 21 September 2018.

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

This overview was last updated in 11-2023.