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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 cancer medicine used in adults to treat:

Non-small cell lung cancer (NSCLC)

Imfinzi is used to treat adults with NSCLC, a type of lung cancer, whose cancer:

- 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;
- 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;
- can be removed by surgery and is at high risk of coming back, when the cancer has no mutations in the *EGFR* gene or other changes, called rearrangements, in the ALK gene. Imfinzi is then used with platinum-based chemotherapy before surgery, and on its own after surgery.

Small cell lung cancer (SCLC)

Imfinzi is used to treat adults with SCLC (a type of lung cancer) whose cancer:

- 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);
- affects one lung, tissues between the lungs and nearby lymph nodes (limited-stage SCLC) and has not worsened after platinum-based chemoradiation therapy (therapy that combines chemotherapy with radiation therapy). Imfinzi is used on its own.

Biliary tract cancer (BTC)

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Imfinzi is used to treat adults with 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 whose cancer has not been treated previously and cannot be removed by surgery or has metastasised.

Hepatocellular carcinoma (HCC)

Imfinzi is used to treat adults with HCC, a type of liver cancer, on its own or in combination with tremelimumab, in patients who have not been treated before and whose disease is advanced or cannot be removed by surgery.

Endometrial cancer

Imfinzi is used to treat adults with endometrial cancer, a cancer of the lining of the womb, when the cancer is advanced or has come back (recurrent). It is used in combination with carboplatin and paclitaxel (chemotherapy medicines) for initial treatment of the disease. For maintenance treatment, it is used on its own when the cancer is mismatch repair deficient (dMMR, meaning that it lacks certain proteins that correct mistakes when DNA in dividing cells is copied) and in combination with olaparib (another cancer medicine) when the cancer is mismatch repair proficient (pMMR, meaning that the repair proteins are present).

Muscle invasive bladder cancer (MIBC)

Imfinzi is used to treat adults with MIBC that can be removed by surgery. MIBC is a type of cancer affecting the bladder (an organ that holds urine) in which the cancer has spread beyond the inner lining of the bladder and into the muscle layer of the bladder wall. Imfinzi is used in combination with gemcitabine and cisplatin (chemotherapy medicines) as preliminary treatment to shrink the cancer (neoadjuvant treatment) before surgery to remove the bladder. Imfinzi is then given on its own after surgery (adjuvant treatment).

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.

How often Imfinzi is given depends on the type of cancer being treated. Treatment generally continues until the disease gets worse or side effects become unacceptable. In some cases, it is given for up to 1 or 2 years.

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, slowing down the progression of the disease.

What benefits of Imfinzi have been shown in studies?

Non-small cell lung cancer

In one main study involving 713 patients with locally advanced NSCLC, 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 a second main study involving 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.

In a third main study involving 802 patients with NSCLC that can be removed by surgery, patients received either Imfinzi plus chemotherapy or placebo with chemotherapy before surgery. After surgery, patients continued with either Imfinzi or placebo for up to 12 cycles of 4 weeks.

The main measures of effectiveness included the time people lived until one of the following events occurred (event-free survival; EFS): the cancer came back; the surgery was no longer considered suitable; the surgery could not be completed; or the patient died. The study also measured the proportion of patients with a pathological complete response, meaning patients had no signs of cancer cells in tissue samples removed during surgery.

Patients given placebo and chemotherapy lived for an average of 26 months before an event occurred. This average time could not yet be calculated for those given Imfinzi and chemotherapy because the number of patients who had had an event was too low at the time of the analysis. At that time, about 27% of the patients in the Imfinzi group and 37% of those in the placebo group had had an event. The results also showed that about 17% of patients given Imfinzi and chemotherapy had a pathological complete response compared with about 4% of those given placebo and chemotherapy.

Small cell lung cancer

In a main study of 805 patients with extensive-stage SCLC, patients given Imfinzi together with chemotherapy lived on average for 13 months compared with 10 months for those given chemotherapy alone.

In another main study, Imfinzi was compared with placebo in 730 patients with limited-stage SCLC whose disease had not progressed following platinum-based chemoradiation therapy. Patients given Imfinzi lived for 55.9 months on average, compared with 33.4 months on average for those given placebo. They also lived longer without their disease getting worse: around 16.6 months on average, compared with 9.2 months on average for patients given placebo.

Biliary tract cancer

In a study involving 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.

Endometrial cancer

A main study consisting of two parts involved 718 patients with advanced or recurrent endometrial cancer who had not been treated before.

In the first part of the study, lasting 6 treatment cycles (18 weeks), two groups of patients were given standard treatment (carboplatin and paclitaxel) plus Imfinzi, and a third group was given standard treatment and placebo. In the second part of the study, patients whose disease had not worsened since starting treatment were included for maintenance treatment. The two groups of patients who received standard treatment plus Imfinzi in the first part of the study were given either Imfinzi in combination with olaparib or Imfinzi with placebo; the group of patients given standard treatment and placebo continued on placebo only.

Patients given standard treatment plus Imfinzi in the first part and Imfinzi and placebo during maintenance treatment lived for 10.2 months on average before their disease got worse. In patients starting on standard treatment plus Imfinzi and continuing on Imfinzi and olaparib maintenance therapy this figure was 15.1 months. Patients given standard treatment with placebo in the first part of the study and placebo during maintenance lived for 9.6 months on average before their disease got worse. Supportive analyses showed a benefit of maintenance therapy with Imfinzi and placebo or Imfinzi with olaparib in patients whose cancer was MMR deficient (dMMR). In patients whose cancer was MMR proficient (pMMR), a benefit was seen with Imfinzi plus olaparib but not with Imfinzi and placebo.

Muscle invasive bladder cancer

In a main study involving 1,083 adults with MIBC that could be removed by surgery, patients were divided into two groups. The first group received Imfinzi in combination with gemcitabine and cisplatin before surgery to remove the bladder and continued with Imfinzi alone after surgery. The second group received gemcitabine and cisplatin before surgery and did not receive any further treatment afterwards. Around 35% of patients given Imfinzi (187 out of 533) had their cancer return, worsen or experienced serious complications including death, 35 months after starting treatment compared to around 47% of those not given Imfinzi, 28 months after starting treatment.

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, diarrhoea, rash, joint pain, fever, abdominal (belly) pain, nose and throat infections, 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 neutropenia (low levels of neutrophils, which fight infections), anaemia (low levels of red blood cells), tiredness, nausea (feeling sick), thrombocytopenia (low levels

of platelets in the blood), hair loss, constipation, decreased appetite, peripheral neuropathy (nerve damage in arms and legs), abdominal (belly) pain, diarrhoea, rash, vomiting, leucopenia (low levels of white blood cells), fever, joint pain, cough, itching, hypothyroidism and increased level of liver enzymes.

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, 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.

When Imfinzi is given together with chemotherapy and followed by Imfinzi with olaparib, the most common side effects (which may affect more than 1 in 5 people) include anaemia, nausea, tiredness, peripheral neuropathy, hair loss, neutropenia, constipation, thrombocytopenia, diarrhoea, vomiting, joint pain, rash, abdominal pain, decreased appetite and leucopenia.

Why is Imfinzi authorised in the EU?

Imfinzi was shown to increase the time patients with locally advanced NSCLC and endometrial cancer lived without their disease getting worse and the time patients with small cell lung cancer, advanced hepatocellular carcinoma or advanced biliary tract cancer lived overall. However, in patients with endometrial cancer, there are uncertainties around the long-term benefits of treatment and these will be addressed in ongoing studies. 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. Imfinzi also showed benefits in patients with NSCLC that can be removed by surgery and is at high risk of coming back; however, long-term data are needed to confirm the effect of treatment on how long patients live overall.

A main study found that for patients with muscle-invasive bladder cancer that could be removed by surgery, adding Imfinzi to standard chemotherapy before and after surgery helped prevent the return or delay the progression of the disease, as well as reduce the risk of death or other cancer-related complications.

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?

The company that markets Imfinzi will provide both the interim and final results of the main study in patients with endometrial cancer to confirm the long-term benefit of the medicine in combination with olaparib in patients whose cancer is MMR proficient, and maintenance therapy with Imfinzi on its own in patients whose cancer is MMR deficient. The company will also provide data on the effect of Imfinzi on how long patients with NSCLC that can be removed by surgery live overall.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Imfinzi have also 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 06-2025.