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# Withdrawal of application to change the marketing authorisation for Imfinzi (durvalumab)

AstraZeneca AB withdrew its application for the use of Imfinzi in the treatment of high-risk non-muscle invasive bladder cancer (NMIBC), a type of cancer that affects the lining of the bladder.

The company withdrew the application on 24 June 2026.

## What is Imfinzi and what is it used for?

Imfinzi is a medicine used to treat several types of cancer, including lung, liver and bile duct cancer. It is also used to treat muscle invasive bladder cancer (MIBC), a type of cancer affecting the bladder (the organ that holds urine), where the cancer has spread beyond the inner lining of the bladder and into the muscle layer of the bladder wall.

Imfinzi has been authorised in the EU since September 2018. It contains the active substance durvalumab and is given by infusion (drip) into a vein.

## What change had the company applied for?

The company applied for an extension of indication to add the treatment of high-risk non-muscle invasive bladder cancer (NMIBC), where the cancer has not spread into the muscle layer but is at high risk of coming back or spreading beyond the inner lining. It was to be used with Bacillus Calmette-Guérin (BCG; a standard bladder cancer treatment that stimulates the immune system) in patients who had not received BCG before.

## 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 disease progression.

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## What did the company present to support its application?

The company presented the results of a main study involving 679 patients with high-risk NMIBC who had not received BCG before. They received either Imfinzi plus BCG or BCG only. The main measure of effectiveness was the time people lived without detectable signs of the disease.

## How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

## What did the Agency recommend at that time?

Based on the review of the information and the company's responses to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Imfinzi could not have been authorised for the treatment of high-risk NMIBC.

The Agency considered that the benefits of adding Imfinzi to BCG in patients with high-risk NMIBC do not outweigh the risks. Although the combination of Imfinzi and BCG was shown to prolong the time people lived without detectable signs of disease, the clinical relevance of the observed effect was uncertain. In addition, there were some limitations in the study design that affected the interpretation of the results. The Agency considered that the observed effect does not outweigh the side effects associated with Imfinzi, which are significantly greater than those with BCG alone.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Imfinzi in the treatment of high-risk NMIBC did not outweigh its risks.

## What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it withdrew its application based on the feedback from the Agency indicating that it would not be able to conclude that the benefits outweigh the risks based on the data provided.

## Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Imfinzi.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

## What is happening with Imfinzi in its authorised uses?

There are no consequences on the use of Imfinzi in its authorised uses.