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Imfinzi approved in the US in first and only immunotherapy combination for patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer

Based on POTOMAC Phase III trial results which showed a 32% reduction in the risk of high-risk disease recurrence, progression or death after one year of Imfinzi added to BCG vs. BCG alone

AstraZeneca's *Imfinzi* (durvalumab) in combination with Bacillus Calmette-Guérin (BCG) induction and maintenance therapy has been approved in the US for the treatment of adult patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC).

The approval by the Food and Drug Administration (FDA) is based on [positive results](#) from the POTOMAC Phase III trial which were presented at the European Society for Medical Oncology (ESMO) Congress 2025 and simultaneously published in [The Lancet](#).

In 2024, over 31,000 people in the US were treated for high-risk NMIBC, a curative-intent setting where the standard of care is tumour resection followed by BCG treatment directly into the bladder.^{1,2} About half of patients with NMIBC are at high-risk for disease recurrence or progression based on certain characteristics of their cancer, such as tumour grade, stage and specific tumour features.³ Up to 80% of high-risk patients experience disease recurrence within five years of treatment.^{3,4}

Neal Shore, MD, FACS, Director of START Carolinas / Head of the Carolina Urologic Research Center and co-principal investigator in the trial, said: "The durvalumab plus BCG regimen is the first new therapy approved in over 30 years for patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer. Unfortunately, many of these patients experience disease recurrence requiring repeated surgical procedures, as well as disease progression resulting in surgical removal of their bladder. The POTOMAC trial demonstrates that the durvalumab with BCG induction and maintenance regimen reduces the risk of disease recurrence, progression or death for patients by almost a third compared to BCG alone, heralding a marked advancement for patients with high-risk non-muscle-invasive bladder cancer."

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: "Today's approval for *Imfinzi* brings the first immunotherapy combination regimen to patients in the US with BCG-naïve, high-risk non-muscle-invasive bladder cancer, an early setting that builds on the positive impact *Imfinzi* is already having in muscle-invasive disease. The early and sustained disease-free survival benefit demonstrated by *Imfinzi* plus BCG in the POTOMAC trial is an important advance for patients at risk of early disease recurrence and signals a shift in the standard of care."

Meri-Margaret Deoudes, CEO of the Bladder Cancer Advocacy Network, said: "It is devastating for patients with high-risk non-muscle-invasive bladder cancer to face the common, early and repeated disease recurrences that are the hallmark of this disease, let alone the prospect of progressing to more advanced disease and life-changing surgeries. New and effective treatment options that address their significant burden are always good news and are urgently needed, so today's approval could offer meaningful hope for patients and their families."

Results from the POTOMAC trial showed adding one year of treatment with *Imfinzi* to BCG induction and maintenance therapy demonstrated a 32% reduction in the risk of high-risk disease recurrence, progression or death in patients with BCG-naïve, high-risk NMIBC compared to BCG alone (based on a disease-free survival (DFS) hazard ratio of 0.68; 95% confidence interval 0.50-0.93; p=0.0154). With a median follow-up of more than five years (60.7 months), the *Imfinzi* regimen delivered an early and sustained DFS benefit starting less than four months after beginning treatment. Estimated median DFS was not yet reached for either arm.

The safety and tolerability of *Imfinzi* plus BCG induction and maintenance therapy was consistent with the known safety profiles of the individual medicines, with no new safety signals identified with a median follow-up of more than five years for DFS. The addition of *Imfinzi* did not compromise patients' ability to complete BCG induction and maintenance therapy and had no meaningful impact on patient-reported quality of life.

Regulatory submissions based on the POTOMAC results are under review in the European Union (EU), Japan and several other countries.

Last week, [positive high-level results](#) from the VOLGA Phase III trial were announced, showing that perioperative treatment with *Imfinzi* in combination with neoadjuvant enfortumab vedotin (EV) demonstrated statistically significant and clinically meaningful improvements in event-free survival (EFS) and overall survival (OS) in patients with muscle-invasive bladder cancer (MIBC) who were ineligible for or had declined cisplatin-based chemotherapy. Perioperative *Imfinzi* plus *Imjudo* (tremelimumab) in combination with neoadjuvant EV demonstrated a statistically significant and clinically meaningful improvement in EFS and a favourable trend for OS; however, the OS data were not statistically significant at this planned interim analysis and will be formally reassessed at a subsequent analysis.

Imfinzi is also approved in several countries for patients with cisplatin-eligible MIBC, based on the NIAGARA Phase III trial, and continues to be investigated in locally advanced or metastatic disease in the NILE Phase III trial.

Notes

Bladder cancer

Bladder cancer is the 9th most common cancer in the world, with more than 614,000 cases diagnosed each year.⁵ The most common type is urothelial carcinoma, which begins in the urothelial cells of the urinary tract.⁶ More than 70% of bladder cancer patients are diagnosed with NMIBC, an early-stage cancer where the tumour is in the tissue that lines the inner surface of the bladder but has not invaded the muscle wall.^{6,7}

Many high-risk NMIBC patients with recurrent disease undergo additional rounds of chemotherapy and repeated invasive procedures such as transurethral resection of bladder tumour (TURBT), and they may ultimately need surgery to remove the bladder (cystectomy). High-risk patients who experience early recurrence and those who become unresponsive to BCG treatment are at a particularly increased risk of disease progression that may require bladder removal, underscoring the critical need for new treatment options in this curative-intent setting.²

POTOMAC

POTOMAC is a randomised, open-label, multi-centre, global Phase III trial evaluating *Imfinzi* in combination with BCG therapy as a treatment for patients with BCG-naïve, high-risk NMIBC who have undergone TURBT prior to randomisation. In the trial, 1,018 patients were randomised 1:1:1 to receive *Imfinzi* plus BCG induction and maintenance therapy, or *Imfinzi* plus BCG induction-only therapy, versus BCG induction and maintenance therapy. In the POTOMAC trial, patients received six weeks of BCG induction therapy with or without two years of BCG maintenance therapy. With median follow-up for DFS exceeding five years, the POTOMAC trial features a notably long observation period among NMIBC trials.

The trial was conducted in more than 120 centres across 12 countries including Canada, Australia, and others across Europe and Asia. The primary endpoint was DFS, defined as time from randomisation to date of first recurrence of high-risk disease, progression or death from any cause, for *Imfinzi* plus BCG induction and maintenance therapy compared to BCG induction and maintenance therapy alone. Secondary endpoints included DFS for *Imfinzi* plus BCG induction only therapy versus the comparator arm, as well as OS at five years and safety across both experimental arms of the trial.

Imfinzi

Imfinzi (durvalumab) is a human monoclonal antibody that binds to the PD-L1 protein and blocks the interaction of PD-L1 with the PD-1 and CD80 proteins, countering the tumour's immune-evading tactics and releasing the inhibition of immune responses.

In addition to its indications in bladder cancer, *Imfinzi* is the global standard of care based on OS in the curative-intent setting of unresectable, Stage III non-small cell lung cancer (NSCLC) in patients whose disease has not progressed after chemoradiotherapy (CRT). Additionally, *Imfinzi* is approved as a perioperative treatment in combination with neoadjuvant chemotherapy in resectable NSCLC, and in combination with a short course of *Imjudo* (tremelimumab) and chemotherapy for the treatment of metastatic NSCLC. *Imfinzi* is also approved for limited-stage small cell lung cancer (SCLC) in patients whose disease has not progressed following concurrent platinum-based CRT; and in combination with chemotherapy (etoposide and either carboplatin or cisplatin) for the treatment of extensive-stage SCLC.

In addition to its indications in lung cancers, *Imfinzi* is approved in combination with chemotherapy (gemcitabine plus cisplatin) in locally advanced or metastatic biliary tract cancer and in combination with *Imjudo* in unresectable hepatocellular carcinoma (HCC). It is also approved as a monotherapy in unresectable HCC in Japan, China and the EU. In resectable gastric and gastroesophageal junction cancers, perioperative *Imfinzi* added to standard-of-care chemotherapy is approved in the US and EU. Additionally, in April 2026, *Imfinzi* in combination with *Imjudo*, lenvatinib and transarterial chemoembolisation (TACE) demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression-free survival versus TACE alone for patients with unresectable HCC eligible for embolisation in the EMERALD-3 Phase III trial.

Imfinzi in combination with chemotherapy followed by *Imfinzi* monotherapy is approved as a 1st-line treatment for primary advanced or recurrent endometrial cancer (mismatch repair deficient disease only in US and EU). *Imfinzi* in combination with chemotherapy followed by *Lynparza* (olaparib) and *Imfinzi* is approved for patients with mismatch repair proficient advanced or recurrent endometrial cancer in EU and Japan.

Since the first approval in May 2017, more than 414,000 patients have been treated with *Imfinzi*. As part of a broad development programme, *Imfinzi* is being tested as a single treatment and in combinations with other anti-cancer treatments for patients with SCLC, NSCLC, bladder cancer, breast cancer, several gastrointestinal and gynaecologic cancers, and other solid tumours.

AstraZeneca in immuno-oncology (IO)

AstraZeneca is a pioneer in introducing the concept of immunotherapy into dedicated clinical areas of high unmet medical need. The Company has a comprehensive and diverse IO portfolio and pipeline anchored in immunotherapies designed to overcome evasion of the anti-tumour immune response and stimulate the body's immune system to attack tumours.

AstraZeneca strives to redefine cancer care and help transform outcomes for patients with *Imfinzi* as a monotherapy and in combination with *Imjudo* as well as other novel immunotherapies and modalities. The Company is also investigating next-generation immunotherapies like bispecific antibodies and therapeutics that harness different aspects of immunity to target cancer, including cell therapy and T-cell engagers.

AstraZeneca is pursuing an innovative clinical strategy to bring IO-based therapies that deliver long-term survival to new settings across a wide range of cancer types. The Company is focused on exploring novel combination approaches to help prevent treatment resistance and drive longer immune responses. With an extensive clinical programme, the Company also champions the use of IO treatment in earlier disease stages, where there is the greatest potential for cure.

AstraZeneca in oncology

AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyse changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

[AstraZeneca](#)

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Contacts

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