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# *Imfinzi* regimen demonstrated statistically significant and clinically meaningful improvement in disease-free survival for high-risk non-muscle-invasive bladder cancer in POTOMAC Phase III trial

***Patients lived significantly longer without high-risk disease recurrence or progression after one year of Imfinzi treatment plus Bacillus Calmette-Guérin (BCG) induction and maintenance therapy vs. BCG alone***

Positive high-level results from the POTOMAC Phase III trial showed one year of treatment with AstraZeneca's *Imfinzi* (durvalumab) plus standard-of-care BCG induction and maintenance therapy demonstrated a statistically significant and clinically meaningful improvement in disease-free survival (DFS) for patients with high-risk non-muscle-invasive bladder cancer (NMIBC) compared to BCG induction and maintenance therapy alone.

The trial was not statistically powered to formally test overall survival (OS) however a descriptive analysis demonstrated no detriment.

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.[1-2] About half of patients with NMIBC are classified as high-risk for disease progression or recurrence because of certain characteristics of their cancer, such as tumour grade, stage and specific tumour features.[3]

Maria De Santis, MD, Head of the Interdisciplinary Uro-Oncology Section at Charité Universitätsmedizin Berlin, Germany, and a principal investigator in the POTOMAC trial, said: "These exciting data show that adding one year of durvalumab to the current standard treatment significantly extends the time patients live without high-risk disease recurrence or progression. While most patients with non-muscle invasive bladder cancer are treated with curative intent, 80 per cent see their disease return and almost half may require life-altering surgery to remove the bladder, underscoring the urgent need to improve treatment."

Cristian Massacesi, Chief Medical Officer and Oncology Chief Development Officer, AstraZeneca, said: "The positive results for *Imfinzi* in the POTOMAC trialrepresent a significant advance that will potentially allow more patients with early-stage bladder cancer to benefit from this important immunotherapy. Building on the NIAGARA data, this outcome demonstrates our strategy of bringing novel therapies to patients with early-stage disease where there is the greatest potential for long-term benefit."

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 concerns identified. The addition of *Imfinzi*did not compromise patients' ability to complete BCG induction and maintenance therapy.

The second experimental arm evaluating *Imfinzi* plus BCG induction-only therapy compared to BCG induction and maintenance therapy alone did not meet the endpoint of DFS.

These data will be presented at a forthcoming medical meeting and shared with global regulatory authorities.

*Imfinzi* is approved in the US and other countries for patients with muscle-invasive bladder cancer (MIBC) based on results from the NIAGARA Phase III trial and continues to be investigated across early and late-stage bladder cancer in various treatment combinations, including in patients with MIBC who are ineligible or refuse to take cisplatin (VOLGA) and in locally advanced or metastatic disease (NILE).

**Notes**

**Bladder cancer**
Bladder cancer is the 9th most common cancer in the world, with more than 614,000 cases diagnosed each year.[4] The most common type is urothelial carcinoma, which begins in the urothelial cells of the urinary tract.[2]

In 2024, an estimated 125,000 patients were treated for high-risk NMIBC, for which the current standard of care is transurethral resection of bladder tumour (TURBT) followed by administration of BCG directly into the bladder.[5-6] Up to 80% of patients experience disease recurrence within five years, and rates of progression in high-risk patients can be as high as 45%.[2] There is a critical need for treatment options in this curative-intent setting.

**POTOMAC**
POTOMAC is a randomised, open-label, multi-centre, global Phase III trial evaluating *Imfinzi* in combination with BCG therapy as a treatment for 1,018 patients with high-risk, BCG-naïve NMIBC who have undergone TURBT prior to randomisation. Patients were randomised 1:1:1 to receive *Imfinzi* plus BCG induction and maintenance therapy, or *Imfinzi* plus BCG induction-only therapy, versus standard-of-care BCG induction and maintenance therapy.

The trial was conducted in more than 120 centres across 12 countries including Canada 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 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 indication in MIBC, *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

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 for the treatment of extensive-stage SCLC.

*Imfinzi* is also approved in combination with chemotherapy in locally advanced or metastatic biliary tract cancer and in combination with *Imjudo* in unresectable hepatocellular carcinoma (HCC). *Imfinzi* is also approved as a monotherapy in unresectable HCC in Japan and the European Union (EU).

In March 2025, perioperative *Imfinzi* added to standard-of-care chemotherapy met the primary endpoint of event-free survival in the MATTERHORN Phase III trial in resectable gastric and gastroesophageal junction cancers.

*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 374,000 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 NSCLC, bladder cancer, breast cancer, ovarian cancer and several gastrointestinal cancers.

**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**
AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on social media @AstraZeneca.

**Contacts**
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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