Imfinzi + EV improves EFS & OS in bladder cancer

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Perioperative *Imfinzi* plus neoadjuvant EV showed statistically significant and clinically meaningful improvements in event-free survival and overall survival in muscle-invasive bladder cancer in the Phase III VOLGA trial

Perioperative Imfinzi plus Imjudo and neoadjuvant EV showed a statistically significant and clinically meaningful improvement in event-free survival and a favourable trend for overall survival

High-level results from a planned interim analysis of the VOLGA Phase III trial showed perioperative treatment with *Imfinzi* (durvalumab) 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) versus standard of care. Patients were ineligible for or had declined cisplatin-based chemotherapy. Patients in the comparator arm had a radical cystectomy (surgery to remove the bladder) with or without approved adjuvant treatment.

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.

Approximately one in four patients with bladder cancer has muscle-invasive disease, where the tumour invades the muscle wall of the bladder, without distant metastases.[1,2] As many as 50% of patients are ineligible for cisplatin-based chemotherapy due to impaired renal function or comorbidities.[3,4] The standard treatment for these patients has historically been radical cystectomy alone but, despite undergoing this major surgery, patients experience high rates of recurrence and have a poor prognosis.[3-5]

Thomas Powles, MD, Professor, Chair of Barts Cancer Centre (QMUL), London, UK, and International Coordinating Investigator for the trial, said: "Up to half of patients with muscle-invasive bladder cancer are not eligible for cisplatin and face high rates of disease recurrence, even after having their bladder removed, leaving a significant need for new effective and well-tolerated treatments. The VOLGA results show that perioperative durvalumab significantly extends event-free survival and overall survival when combined with neoadjuvant enfortumab vedotin, with a manageable safety profile, compared to surgery for patients in this curative-intent setting."

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "This interim analysis from the VOLGA trial highlights the benefit of perioperative *Imfinzi* with neoadjuvant enfortumab vedotin compared to surgery, a novel regimen that optimises treatment options for patients. Together with NIAGARA and POTOMAC, VOLGA is our third positive readout in bladder cancer, setting a strong foundation for *Imfinzi* as the immunotherapy backbone in this early-stage, curative-intent setting."

The safety and tolerability of *Imfinzi* with or without *Imjudo* plus EV was consistent with the known safety profiles of the individual medicines, with no new safety signals identified. These data will be presented at a forthcoming medical meeting and shared with global regulatory authorities.

Imfinzi is approved in over 40 countries for patients with cisplatin-eligible MIBC, based on the NIAGARA Phase III trial. Additionally, *Imfinzi* added to Bacillus Calmette-Guérin therapy met the primary endpoint of disease-free survival for patients with high-risk non-muscle-invasive bladder cancer in the POTOMAC Phase III trial and is currently under review in the US, European Union (EU), Japan and several other countries. *Imfinzi* is also being 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.[6] The most common type is urothelial carcinoma, which begins in the urothelial cells of the urinary tract.[7]

In 2024, an estimated 117,500 patients were treated for MIBC with the standard of care, which included neoadjuvant cisplatin-based chemotherapy and radical cystectomy.[5,8] In 2025, the NIAGARA Phase III trial established a new standard by adding perioperative *Imfinzi* to the regimen.[9] However, up to half of patients are not eligible to receive cisplatin, and approximately 50% of MIBC patients who undergo bladder removal surgery experience disease recurrence.[3,5] New treatment options that prevent both progression before surgery and recurrence after surgery are critically needed in this curative-intent setting.

VOLGA

VOLGA is a Phase III, randomised, open-label, multi-centre global trial evaluating perioperative *Imfinzi* with or without *Imjudo* in combination with neoadjuvant EV as treatment for patients with MIBC undergoing radical cystectomy who are not eligible for or have declined cisplatin compared to radical cystectomy with or without approved adjuvant therapy. In the trial, 695 patients were randomised 1:1:1 to Arm 1 (three cycles of *Imfinzi* and EV, plus two cycles of *Imjudo* prior to surgery, followed by nine cycles of *Imfinzi* plus one cycle of *Imjudo* as adjuvant therapy), Arm 2 (three cycles of *Imfinzi* and EV prior to surgery, followed by nine cycles of *Imfinzi* adjuvant monotherapy) and Arm 3, the comparator arm.

The trial was conducted in 182 centres across 25 countries in Europe, North America, South America and Asia. Its dual primary endpoints are EFS, defined as the time from randomisation to first recurrence post-radical cystectomy, first progression in patients who did not undergo radical cystectomy, failure to undergo radical cystectomy in patients with residual disease or death due to any cause, for both experimental arms versus the comparator arm. Secondary endpoints include OS (Arm 1 vs. Arm 3 and Arm 2 vs. Arm 3), pathologic complete response, disease-free survival and pathologic downstaging across both experimental arms.

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 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). *Imfinzi* is also approved as a monotherapy in unresectable HCC in Japan 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.

Imjudo
Imjudo (tremelimumab) is a human monoclonal antibody that targets the activity of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4). *Imjudo* blocks the activity of CTLA-4, contributing to T-cell activation, priming the immune response to cancer and fostering cancer cell death. In addition to its approved indications in liver and lung cancers, *Imjudo* is being tested in combination with *Imfinzi* across other tumour types including SCLC (ADRIATIC) and bladder cancer (NILE).

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/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Disease, 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

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