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Imfinzi plus _Imjudo_ combined with lenvatinib and TACE demonstrated a statistically significant and clinically meaningful improvement in progression-free survival in embolisation-eligible unresectable liver cancer in EMERALD-3 Phase III trial

Imfinzi plus Imjudo combined with lenvatinib and transarterial chemoembolisation (TACE) showed trend toward improved overall survival

Positive high-level results from the EMERALD-3 Phase III trial showed AstraZeneca's *Imfinzi* (durvalumab) in combination with *Imjudo* (tremelimumab), lenvatinib and transarterial chemoembolisation (TACE) demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) versus TACE alone for patients with unresectable hepatocellular carcinoma (HCC) eligible for embolisation.

At this interim analysis for overall survival (OS), a key secondary endpoint, this combination also demonstrated a trend toward OS improvement versus TACE alone.

Patients in the investigational arms were treated with the STRIDE regimen (Single Tremelimumab Regular Interval Durvalumab), with or without lenvatinib, before TACE, and then alongside TACE.

Although not formally tested at this time, data for the treatment arm evaluating the STRIDE regimen plus TACE versus TACE alone showed strong trends toward improved PFS and OS. The trial will continue to follow OS and other key secondary endpoints in both investigational arms.

HCC is the most common type of liver cancer.[1] In 2026, more than 200,000 patients with HCC will be eligible for embolisation, a standard-of-care procedure that blocks the blood supply to the tumour and can also deliver chemotherapy directly to the liver.[2-4] However, most patients who receive embolisation experience disease progression or recurrence within six to ten months.[5]

Ghassan Abou-Alfa, MD, JD, MBA, PhD(hc), Attending Physician, Professor of Medicine at Memorial Sloan Kettering Cancer Center, and principal investigator in the trial said, "Dual immunotherapy with durvalumab and tremelimumab in the STRIDE regimen represents a meaningful advance for patients with embolisation-eligible liver cancer, who currently lack systemic treatment options to keep their cancer from progressing or recurring, with a trend of improving survival. EMERALD 3 shows we can now significantly reduce the risk of disease progression with STRIDE as the immunotherapy backbone alongside lenvatinib and TACE."

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "EMERALD 3 now shows that bringing the dual immunotherapy STRIDE regimen earlier, alongside TACE and lenvatinib, can further improve outcomes in earlier stage liver cancer. This builds on the HIMALAYA Phase III trial data in patients with advanced, unresectable disease, where the STRIDE regimen has already demonstrated durable overall survival benefit. We are discussing these positive data with global regulatory authorities while awaiting the final results from the key secondary endpoints."

The safety profile for each combination was consistent with the known profiles of each medicine, and there were no new safety findings.

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

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Notes

Liver cancer
Liver cancer, of which HCC is the most common type, is the third-leading cause of cancer death.[1,6] In 2026, more than 200,000 patients will be diagnosed with embolisation-eligible HCC.[2] Embolisation is a standard-of-care procedure that blocks the blood supply to the tumour and can also deliver chemotherapy directly to the liver.[3-4]

Immunotherapy is a proven treatment modality in HCC with approved options available for patients in later-line settings.[7]

EMERALD-3
EMERALD-3 is a randomised, open-label, sponsor-blinded, multicentre, global Phase III trial of a single priming dose of *Imjudo* 300mg added to *Imfinzi* 1500mg followed by *Imfinzi* every four weeks (STRIDE regimen) plus TACE with or without lenvatinib versus TACE alone in a total of 760 patients with unresectable HCC eligible for embolisation.

Participants were randomised in a 1:1:1 ratio to Arm A (TACE, *Imfinzi*, *Imjudo*, lenvatinib), Arm B (TACE, *Imfinzi*, *Imjudo*) and Arm C (TACE) until each arm reached 175 participants. Randomisation was then continued in a 1:1 ratio to treatment Arms A and C until each reached approximately 275 participants. Patients received *Imfinzi* with *Imjudo,* plus TACE as needed, with or without lenvatinib concurrently, followed by *Imfinzi* with or without lenvatinib until progression.

The trial was conducted in 171 centres across 22 countries, including in North America, Europe, South America and Asia. The primary endpoint is PFS for *Imfinzi* plus *Imjudo*, lenvatinib and TACE versus TACE alone. Secondary endpoints include OS for *Imfinzi* plus *Imjudo*, lenvatinib and TACE, and PFS and OS for *Imfinzi* plus *Imjudo* and TACE versus TACE alone.

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 gastrointestinal (GI) cancer, *Imfinzi* is approved in combination with chemotherapy in locally advanced or metastatic biliary tract cancer (BTC) and in combination with *Imjudo* in unresectable HCC. *Imfinzi* is also approved as a monotherapy in unresectable HCC in Japan and the EU.

In addition to its indications in GI cancers, *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* 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.

Perioperative *Imfinzi* in combination with neoadjuvant chemotherapy is approved in the US, EU, Japan and other countries for patients with muscle-invasive bladder cancer based on results from the NIAGARA Phase III trial. Additionally, in May 2025, *Imfinzi* added to Bacillus Calmette-Guérin induction and maintenance 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.

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 the 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 the 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 NSCLC, bladder cancer, breast cancer, ovarian cancer and several GI cancers.

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 multiple tumour types including in SCLC (ADRIATIC) and bladder cancer (VOLGA and NILE).

AstraZeneca in GI cancers
AstraZeneca has a broad development programme for the treatment of GI cancers across several medicines and a variety of tumour types and stages of disease. In 2022, GI cancers collectively represented approximately 5 million new cancer cases leading to approximately 3.3 million deaths.[8]

Within this programme, the Company is committed to improving outcomes in gastric, liver, biliary tract, oesophageal, pancreatic and colorectal cancers.

In addition to its indications in BTC and HCC, *Imfinzi* is being assessed in combinations, including with *Imjudo*, in oesophageal and gastric cancers in an extensive development programme spanning early to late-stage disease across settings.

Enhertu (trastuzumab deruxtecan), a HER2-directed antibody drug conjugate (ADC), is approved in the US and several other countries for HER2-positive advanced gastric cancer. *Enhertu* is jointly developed and commercialised by AstraZeneca and Daiichi Sankyo.

Lynparza, a first-in-class PARP inhibitor, is approved in the US and several other countries for the treatment of BRCA-mutated metastatic pancreatic cancer. *Lynparza* is developed and commercialised in collaboration with MSD (Merck & Co., Inc. inside the US and Canada).

The Company is also assessing rilvegostomig, a PD-1/TIGIT bispecific antibody, in combination with chemotherapy as an adjuvant therapy in BTC, in combination with bevacizumab with or without *Imjudo* as a 1st-line treatment in patients with advanced HCC, and as a 1st-line treatment in patients with HER2-negative, locally advanced unresectable or metastatic gastric and gastroesophageal junction cancers. Rilvegostomig is also being evaluated in combination with *Enhertu* in previously untreated, HER2-expressing, locally advanced or metastatic BTC.

AstraZeneca is advancing multiple modalities that provide complementary mechanisms for targeting Claudin 18.2, a promising therapeutic target in gastric cancer. These include sonesitatug vedotin, a potential first-in-class ADC licensed from KYM Biosciences Inc., currently in Phase III development; AZD5863, a novel Claudin 18.2/CD3 T-cell engager bispecific antibody licensed from Harbour Biomed in Phase I development; and AZD4360, an ADC, currently being evaluated in a Phase I/II trial in patients with advanced solid tumours.

In early development, AstraZeneca is developing AZD7003, a Glypican 3 (GPC3) armoured CAR T, in HCC.

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

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 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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Dr. Abou-Alfa provides consulting and advisory services to AstraZeneca.

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