

17 August 2026

Update on eVOLVE-Lung02 Phase III trial of volrustomig plus chemotherapy in metastatic non-small cell lung cancer

AstraZeneca is discontinuing the eVOLVE-Lung02 Phase III trial evaluating volrustomig in combination with chemotherapy as a 1st-line therapy compared to pembrolizumab and chemotherapy in patients with metastatic non-small cell lung cancer (mNSCLC) whose tumours express PD-L1 <50%.

This decision is based on the recommendation of the Independent Data Monitoring Committee (IDMC) following a planned review of trial data. The IDMC concluded that the volrustomig combination was unlikely to meet either of the dual primary endpoints of progression-free survival (PFS) or overall survival (OS) in the primary analysis population of patients with PD-L1 negative tumours (<1%) versus the comparator arm.

The safety profile of volrustomig plus chemotherapy was consistent with the known profiles of the individual medicines and no new safety signals were identified.

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "We initiated the eVOLVE-Lung02 trial aiming to improve the outcomes for patients whose lung cancers have lower PD-L1 expression and a less durable response to current immunotherapy regimens. While we are disappointed, we will learn from this trial and are determined to continue pioneering new medicines from our industry-leading pipeline in our quest to improve outcomes for patients with lung cancer."

The Company will work with investigators to ensure continuity of care and appropriate follow up for patients on the trial. The other Phase III volrustomig trials continue as planned in cervical cancer, head and neck squamous cell carcinoma and mesothelioma.

Notes

NSCLC

Lung cancer is the leading cause of death by cancer globally, accounting for almost one in four (23%) cancer deaths.¹ Lung cancer is broadly split into small cell lung cancer or NSCLC, the latter accounting for 80-85% of cases.^{1,2} Patients are most commonly diagnosed with metastatic disease, when the tumour has spread outside the lung.³ Approximately 12% of people with metastatic NSCLC will still be alive five years after diagnosis.⁴

eVOLVE-Lung02

eVOLVE-Lung02 is a randomized, open-label, multi-centre, global Phase III trial of volrustomig plus chemotherapy for 1st-line treatment of patients with mNSCLC whose tumours express PD-L1 <50%. Patients were randomized 1:1 to receive 750mg intravenous volrustomig in combination with chemotherapy every three weeks for four cycles followed by volrustomig every three weeks, or 200mg pembrolizumab plus chemotherapy every three weeks for four cycles followed by pembrolizumab every three weeks until completion of 24 months of treatment or disease progression, or other discontinuation criterion are met.

The trial enrolled 895 patients across 25 countries. The dual primary endpoints were progression-free survival (PFS) and overall survival (OS) in patients whose tumours express PD-L1 <1%. Secondary endpoints included PFS and OS in the intent-to-treat population (PD-L1 <50%).

Volrustomig

Volrustomig is a dual checkpoint inhibitor bispecific antibody designed to deliver coordinated and targeted PD-1 and CTLA-4 blockade on the same T cell. AstraZeneca is evaluating volrustomig as monotherapy and in combinations in several tumour types with high unmet need.

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](https://twitter.com/AstraZeneca).

Contacts

For details on how to contact the Investor Relations Team, please click [here](#). For Media contacts, click [here](#).

References

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