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Health Technology Briefing
April 2026

Osimertinib for treating EGFR-mutated stage IA2-IA3 non-small-cell lung cancer following complete tumour resection

Company/Developer	AstraZeneca

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 34381	NICE ID: Not available	UKPS ID: 670189

Licensing and Market Availability Plans

Currently in phase III clinical development.

Summary

Osimertinib is in development for the treatment of patients with epidermal growth factor receptor (EGFR) mutation positive early stage (IA2-IA3) non-small cell lung cancer (NSCLC) after complete surgical removal of the tumour. NSCLC accounts for around 80-85% of lung cancers in the UK, with the EGFR mutation being one of the most commonly seen mutations in NSCLC. The EGFR mutation leads to incorrect versions of the EGFR proteins being produced by cancer cells, allowing these cells to grow and spread. Certain factors can increase the risk of developing lung cancer, including: smoking tobacco, exposure to radiation or certain chemicals, as well as family history of lung cancer.

Osimertinib is given in the form of an oral tablet once a day. It is a tyrosine kinase inhibitor, which binds to and irreversibly blocks the mutant EGFR proteins, preventing their tumour encouraging effects on cells. When given to a patient following the surgical removal of their tumour, it has the potential to reduce the risk of the cancer growing back. If approved, osimertinib may offer an additional treatment option for patients with EGFR mutation positive, early-stage NSCLC, after the surgical removal of a tumour.

Proposed Indication

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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For the treatment of adult patients with epidermal growth factor receptor (EGFR) mutant stage IA2-IA3 non-small-cell lung cancer (NSCLC) following complete tumour resection.[1]

Technology

Description

Osimertinib (TAGRISSO) is a tyrosine kinase inhibitor (TKI). It is an irreversible inhibitor of EGFRs harbouring sensitising-mutations (EGFRm) and TKI-resistance mutation T790M.[2] It is a third-generation TKI that is specific for the gate-keeper T790M mutation which increases adenosine triphosphate binding activity to EGFR and results in poor prognosis for late-stage disease. Furthermore, osimertinib has been shown to spare wild-type EGFR during therapy, thereby reducing non-specific binding and limiting toxicity.[3]

Osimertinib is in development for the treatment of EGFR positive, stage IA2-IA3, NSCLC following complete tumour resection. In the phase III clinical trial ADAURA2, osimertinib is administered as an 80mg oral tablet, once daily (which can be reduced to 40mg as needed).[1]

Key Innovation

The standard of care for patients with resectable NSCLC is surgical resection, often followed by pharmacological treatments.[4] However, the benefits of these pharmacological treatments following surgery is limited, and the risk of recurrence remains high and increases with disease stage.[5-7] There is data to suggest that patients with EGFRm– NSCLC have a greater risk of recurrence after postoperative chemotherapy compared to those with EGFR wild-type NSCLC.[8,9] Unlike earlier-generation EGFR-TKIs, osimertinib inhibits the common T790M resistance mutation found un NSCLC and has improved target engagement for EGFR-TKI–sensitising mutations, which leads to enhanced tumour shrinkage.[10,11] In another phase III clinical trial (ADAURA), osimertinib provided a significant overall survival benefit among patients with completely resected, EGFRm, stage IB to IIIA NSCLC.[12] If licensed, osimertinib will offer an additional treatment option for patients with EGFRm stage IA2-IA3 NSCLC following complete tumour resection.

Regulatory & Development Status

Osimertinib currently has Marketing Authorisation in the EU/UK for the following indications:[2]

- adjuvant treatment following complete tumour resection in adult patients with stage IB-IIIA NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations
- treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, when disease has not progressed during or following platinum-based chemoradiation therapy
- treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC
- in combination with pemetrexed and platinum-based chemotherapy for the treatment of adult patients with advanced NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations

Osimertinib is also in phase II and/or III clinical development for brain metastases.[13]

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Osimertinib has the following regulatory designations/awards; [14,15]

- FDA breakthrough therapy designation in 2020 for the adjuvant treatment of patients with Stage IB-IIIA EGFR-mutated lung cancer
- FDA Orphan drug designation in 2014 for the treatment of EGFR

Patient Group

Disease Area and Clinical Need

Lung cancer is classified into two main histologic types: small cell lung cancer or NSCLC. NSCLC comprises about 80-85% of lung cancers in the UK.[16] Cancers are often broken down into 'stages' to indicate their severity and their spread about the body. For NSCLC, stage IA2 and IA3 indicate that the tumour is relatively small and non-invasive and has not spread to the surrounding tissues of the lung or any further tissues.[17] The EGFR mutation is one of the most common mutations in NSCLC. The EGFR gene controls the production of EGFR proteins. When cancer cells test positive for the EGFR protein, it means that the EGFR gene contains a mutation and is sending faulty instructions to the cells. These mutations allows cancer to grow and spread.[18] Certain factors can increase the risk of developing lung cancer, including: smoking tobacco, exposure to radiation (by exposure to radon gas and previous radiotherapy treatment), exposure to certain chemicals (e.g. asbestos, silica and diesel engine exhaust fumes), previous lung disease (e.g. chronic obstructive pulmonary disease), as well as family history of lung cancer and certain genetic mutations.[19] Symptoms of lung cancer include a persistent cough (which may be more painful, have a different sound or bring up coloured mucus), shortness of breath, coughing up blood, aches and pains in the chest or shoulder, loss of appetite, weight loss and fatigue.[20]

Lung cancer is the third most common cancer in the UK, accounting for 13% of all new cancer cases (2017 - 2019). There are approximately 49,300 new lung cancer cases in the UK every year (2017-2019). Incidence rates for lung cancer in the UK are highest in people aged 85 to 89 (2017-2019). Lung cancer is the most common cause of cancer death in the UK, accounting for 20% of all cancer deaths (2021-2023).[21] In England, 2024-25, there were 128,356 finished consultant episodes (FCE) and 108,616 admissions for malignant neoplasm of bronchus and lung (ICD-10 code C34) which resulted in 220,624 FCE bed days and 83,351 day cases.[22]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) currently recommends osimertinib for adjuvant treatment of EGFR mutation-positive stage 1b-3a NSCLC after complete tumour resection.[23]

Clinical Trial Information

Trial	**ADAURA2; 2023-509943-28-00; NCT05120349;** A phase III, double-blind, randomised, placebo-controlled, international study to assess the efficacy and safety of adjuvant osimertinib versus placebo in participants with EGFR mutation-positive Stage IA2-IA3 Non-small Cell Lung Cancer, following complete tumour resection **Phase III** - Active, not recruiting **Location(s) –** 5 EU countries, UK, USA, Canada and other countries **Primary completion date –** August 2027
Trial Design	Randomised, double-blinded, placebo-controlled

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Population	Adults aged 18 years and older, with a diagnosis of non-squamous NSCLC, that is stage IA2 or IA3, following complete surgical resection of the primary NSCLC by lobectomy, bilobectomy, segmentectomy or sleeve resection.
Intervention(s)	80mg oral osimertinib, once daily (dose may be reduced to 40 mg once daily if required)
Comparator(s)	80mg oral placebo once daily (initial dose of 80mg can be reduced to 40mg)
Outcome(s)	Primary outcome measure: • Disease-free survival in high-risk stratum [Timeframe: from date of randomisation up to approximately 10 years] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Osimertinib is already marketed in the UK for the treatment of NSCLC a pack of 30 x 40mg or 30 x 80mg tablets costs £5,770.[24]

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection (TA1037). February 2025.
- NICE clinical guideline. Lung cancer: diagnosis and management (NG122). March 2019. Last updated March 2024.
- NICE guideline. Suspected cancer: recognition and referral (NG12). October 2023.
- NICE quality standard. Lung cancer in adults (QS17). March 2012. Updated December 2019.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard Contract for Cancer: Chemotherapy (Adult). B15/S/a.
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- NHS England. Clinical Commissioning Policy: Proton Beam Therapy for Lung Cancer (Adults). 201201P. February 2021.
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- NHS Commissioning Board. Clinical Commissioning Policy: Stereotactic ablative body radiotherapy for non-small-cell lung cancer (Adult). NHSCB/B01/P/a. April 2013.

Other Guidance

- National Comprehensive Cancer Network (NCCN). Guidelines Insights: Non–Small Cell Lung Cancer, Version 3.2025.[25]
- European Society for Medical Oncology (ESMO). Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2018.[26]

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