medicines patent pool

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OSIMERTINIB

ONCOLOGY
LUNG CANCER

AstraZeneca

DISEASE BURDEN

In 2022, globally, lung cancer was responsible for 2.48 million new cases and 1.8 million deaths. 80% are classified as non-small cell lung cancers (NSCLC). The EGFR mutation is present in 30% of these cases and almost 60% of these cases are diagnosed in advanced stages.

CLINICAL RELEVANCE

Osimertinib, a third generation EGFR-TKI, is the preferred option for the treatment of early stages of locally advanced NSCLC and for treatment of metastatic NSCLC with EGFR-activating mutation. Patients who received osimertinib had longer overall survival than those who received gefitinib, a first generation EGFR TKI.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on osimertinib is expected to expire in 2032 and has been granted in more than 60 LMICs.

SERVICE DELIVERY ENABLERS

Lung cancer is still underdiagnosed in many LMICs, especially where there is a higher burden of tuberculosis. While basic imaging tests are available in the public sector of LMICs, patients are often identified at an advanced/metastatic setting. EGFR PCR testing is becoming increasingly available also in the public sector of some LMICs, including thanks to the availability of generic first and second generation of EFGR TKIs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of osimertinib could rely on mechanisms like USFDA Paragraph III, Swissmedic MAGHP, EU-M4all for quality assurance. Bioequivalence studies will be required. Biowaivers might not be possible.

MANUFACTURING

The product requires a standard manufacturing process for tablets. There are no anticipated challenges in relation to excipients or final packaging. Due to probable occupational exposure band (OEB) category 4, a special facility might be required. Shelf life is three years at room temperature.

MARKET

Osimertinib is available in some LMICs primarily in the private sector. It is one of the costliest medicines in the NSCLC segment and is generally not affordable to most people with lung cancer in LMICs. Access plans of osimertinib are not known yet.

EGFR-TKI: Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor; EU-M4All: The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure is called EU-Medicines for all or 'EU-M4all'; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; NSCLC: non-small cell lung cancer; PCR: Polymerase Chain Reaction; OEB: occupational exposure band; Swissmedic MAGHP: Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products; USFDA: The United States Food and Drug Administration