medicines patent pool

PRIORITY LIST

OSIMERTINIB

ONCOLOGY
LUNG CANCER

Astrazeneca

DISEASE BURDEN

Lung cancer is the most commonly diagnosed and the first cause of death from cancer worldwide, with an estimated 2.2 million new cases and 1.7 million related deaths in 2020. 80% are classified as non-small cell 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 3rd generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (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 1st 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. Basic imaging tests are available in the public sector of LMICs however, patients are often identified at an advanced/metastatic setting. EFGR PCR testing is becoming increasingly available also in the public sector of LMICs, also 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

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable occupational exposure band (OEB) category 4, special facility might be required. Shelf life is 3 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.