medicines patent pool

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AUMOLERTINIB

ONCOLOGY
LUNG CANCER

Hansoh Pharma

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

Aumolertinib, an investigational third generation EGFR-TKI, has demonstrated a consistent benefit in the time a patient can live without disease progression and a lower rate of adverse events leading to permanent discontinuation, compared to gefitinib, a first generation EGFR TKI.

INTELLECTUAL PROPERTY LANDSCAPE

Aumolertinib compound patent is expected to expire in 2035, and it has been granted in key countries of manufacture such as India, China and South Africa. Secondary patents may provide exclusivity in a few LMICs until 2036-2039.

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

Aumolertinib is not yet approved by stringent regulatory authorities. There is currently insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MARKET

Aumolertinib is currently approved only in a few countries. Access plans for it in LMICs are currently unknown.

EGFR-TKI: Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor ; 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