medicines patent pool

PRIORITY LIST

AUMOLERTINIB

ONCOLOGY
LUNG CANCER

Revolution Medicines

DISEASE BURDEN

Lung cancer is the most 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

Aumolertinib, an investigational 3rd generation epidermal growth factor receptor tyrosine kinase inhibitor (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.

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 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, also thanks to the availability of generic first and second generation of EFGR TKIs.

REGULATORY

Aumolertinib does not have SRA approval yet and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

Limited data available to assess the manufacturing complexity of aumolertinib.

MARKET

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