LAZERTINIB

ONCOLOGY
LUNG CANCER

Janssen

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

Lazertinib, a 3rd generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), demonstrated significant improvement in the time a patient can live without disease progression compared with gefitinib, a 1st generation EGFR TKI.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on lazertinib has been granted in many LMICs including India and is expected to expire in 2034. There are secondary patents that may provide further exclusivity until 2038-2041 in many 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 stage. 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

Lazertinib is only approved in the Republic of Korea so far and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

There is currently limited data available to assess the manufacturing complexity of lazertinib.

MARKET

Although the product got its first approval in 2021, it is still pricier than first-generation EGFR TKI inhibitors. There is no information on its access and availability in LMICs