

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). Activating mutations in KRAS viral oncogene homologue are found in 25 to 30% of NSCLC.

CLINICAL RELEVANCE

Sotorasib significantly increased the time a patient, with advanced NSCLC presenting the KRAS mutation, can live without disease progression and had a more favourable safety profile compared with docetaxel, a conventional chemotherapy drug.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on sotorasib has been granted in many LMICs and is expected to expire in 2038. Several secondary patents on crystalline forms and processes are expected to expire between 2039 and 2040.

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. PCR testing capacity is becoming increasingly available also in the public sector of LMICs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of sotorasib could rely on mechanisms like USFDA Paragraph III, Swissmedic MAGHP, EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable OEB category 3, manufacturing precautions necessary. Shelf life is 3 years at room temperature.

MARKET

The drug is currently available in very few LMICs and is generally pricier than standard of care. Access plans are currently unknown

SOTORASIB

ONCOLOGY
LUNG CANCER

Amgen