



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 nonsmall cell lung cancers (NSCLC). Activating mutations in KRAS viral oncogene homologue are found in 25 to 30% of NSCLC.

CLINICAL RELEVANCE

Adagrasib led to durable clinical benefit in patients with previously treated, advanced KRASG12C-mutated NSCLC. Adagrasib is being evaluated as monotherapy and in combination with other therapies in NSCLC.



INTELLECTUAL PROPERTY LANDSCAPE

Adagrasib primary patents have been filed in many LMICs and are expected to expire in 2038.



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





Mirati

REGULATORY

The product is approved by stringent regulatory authorities. Potential sublicensees of adagrasib could rely on mechanisms like USFDA Paragraph III 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. Occupational Exposure Limit (OEL) is not known. Shelf life is at least 2 years at room temperature.



Adagrasib is Mirati's first commercial product, approved in very few countries (none of which are LMICs). Access plans are not known yet.



