USFDA approves new TB drug, first in 40 years

WASHINGTON: US health authorities have approved a new medicine to fight multi-drug resistant TB, the first to be approved in the country in more than four decades.

The US Food and Drug Administration (FDA) approved the new drug Sirturo (bedaquiline) as part of combination therapy to treat adults with multi-drug resistant pulmonary tuberculosis (TB) when other alternatives are not available.

TB is an infection caused by Mycobacterium tuberculosis and is one of the world's deadliest diseases. It is spread from person to person through the air and usually affects the lungs, but it can also affect other parts of the body such as the brain and kidneys.

According to the Centers for Disease Control and Prevention, nearly 9 million people around the world and 10,528 people in the United States became sick with TB in 2011.

Multi-drug resistant TB occurs when M tuberculosis becomes resistant to isonazid and rifampin, two powerful drugs most commonly used to treat TB.

Sirturo is the first drug approved to treat multi-drug resistant TB and should be used in combination with other drugs used to treat TB.

The new drug works by inhibiting an enzyme needed by M tuberculosis to replicate and spread throughout the body.

Two Phase 2 clinical trials in 440 patients determined the safety and effectiveness of the drug.

Patients in the first trial were randomly assigned to be treated with Sirturo plus other drugs used to treat TB, or a placebo plus other drugs used to treat TB.

All patients in the second trial, which is ongoing, received Sirturo plus other TB drugs. Both studies were designed to measure the length of time it took for a patient's sputum to be free of M tuberculosis (sputum culture conversion, or SCC).

Results from the first trial showed patients treated with Sirturo combination therapy achieved SCC in a median time of 83 days, compared with 125 days in patients treated with placebo combination.
therapy.

Results from the second trial showed the median time to SCC was 57 days, supporting the efficacy findings of the first trial.

Common side effects identified in the clinical trials include nausea, joint pain, and headache.

"Multi-drug resistant tuberculosis poses a serious health threat throughout the world, and Sirturo provides much-needed treatment for patients who have don't have other therapeutic options available," Edward Cox, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research, said in a statement.

The drug carries a warning alerting patients and health care professionals that the drug can affect the heart's electrical activity (QT prolongation), which could lead to an abnormal and potentially fatal heart rhythm.

The drug manufacturer, Janssen Therapeutics, will distribute the drug from a single source.

Source: Economic Times