The FDA Recommends Fast-Track Approval for TB Therapy in New Drug Class

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The U.S. Food and Drug Administration's (FDA) Anti-Infective Drugs Advisory Committee has recommended accelerated approval for bedaquiline, the first in a new class of tuberculosis (TB) therapy, aidsmap reports. The committee voted unanimously to support the new agent's indication as a treatment for multidrug resistant (MDR) TB, and a majority voted that the safety findings of clinical trials supported this indication.

Internationally, and especially in sub-Saharan Africa, TB is a leading infectious killer, in particular among people with HIV. Many global efforts to fight HIV also focus on TB.

In a Phase II trial, researchers at the Faculty of Health Sciences at Stellenbosch University in Tygerberg, South Africa, conducted an eight-week randomized placebo-controlled study of 47 patients with MDR pulmonary tuberculosis and published their findings in Antimicrobial Agents and Chemotherapy. Twenty-three patients received bedaquiline, and 24 patients received a placebo. All patients also received a standard drug regimen for MDR-TB. After eight weeks of treatment, 48 percent of those on bedaquiline became sputum-negative, compared with only 9 percent of those on the placebo.

To read the aidsmap story, click here.

To read the study abstract, click here.

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