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FDA approves new drug for resistant TB

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Approval marks the second drug approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs

The U.S. Food and Drug Administration (FDA) has approved Pretomanid Tablets in combination with bedaquiline and linezolid for the treatment of a specific type of highly treatment-resistant tuberculosis (TB) of the lungs.

Pretomanid in combination with bedaquiline and linezolid is approved for treating a limited and specific population of adult patients with extensively drug resistant, treatment-intolerant or nonresponsive multidrug resistant pulmonary TB.

The FDA granted the approval of Pretomanid Tablets to The Global Alliance for TB Drug Development (TB Alliance). With this approval, The Global Alliance for TB Drug Development is awarded a Tropical Disease Priority Review Voucher in accordance with a provision included in the Food and Drug Administration Amendments Act of 2007 that aims to encourage development of new drugs and biological products for the prevention and treatment of certain tropical diseases.

Pretomanid is the second drug to be approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD pathway, established by Congress under the 21st Century Cures Act to advance development and approval of antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need.

Pretomanid also received the FDA's Qualified Infectious Disease Product (QIDP) designation. The QIDP designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.