U.S. Food and Drug Administration (FDA) Approves Pretomanid

On August 14, 2019 the FDA granted approval for Pretomanid Tablets to the nonprofit Global Alliance for TB Drug Development (TB Alliance). Pretomanid is approved for use as part of a three-drug regimen with bedaquiline and linezolid to treat adults with pulmonary extensively drug-resistant (XDR), or to treat intolerant or nonresponsive multidrug-resistant (MDR) TB[1]. The three-drug, six-month, all oral regimen is also referred to as BPal (for bedaquiline, pretomanid and linezolid).

As described in the FDA press release announcing the approval, "the safety and effectiveness of Pretomanid, taken orally in combination with bedaquiline and linezolid, was primarily demonstrated in a study of 109 patients with extensively drug-resistant, treatment intolerant or non-responsive multidrug-resistant pulmonary TB (of the lungs). Of the 107 patients who were evaluated six months after the end of therapy, 95 (89 percent) were successes, which significantly exceeded the historical success rates for treatment of extensively drug resistant TB."

In April 2019, TB Alliance granted a non-exclusive, worldwide license to pharmaceutical company Mylan for the manufacture and commercialization of Pretomanid. The drug is expected to be available in the U.S. by the end of calendar year 2019[2].

Pretomanid is the second drug to be approved under the Limited Population for Antibacterial and Antifungal Drugs (LPAD) Pathway. This was added to the Federal Food, Drug and Cosmetic Act by Section 3042 of the 21st Century Cures Act enacted by the U.S. Congress in 2016. The intent of the LPAD Pathway is to facilitate the development of antibacterial (and antifungal) drug products that treat serious or life-threatening infections.

TB clinicians are advised to contact the PA TB Program as soon as they suspect a patient has MDR or XDR TB. Treatment decisions for such patients should be made in consultation with the PA TB medical consultants and clinicians at the Global TB Institute at Rutgers, a CDC-funded TB Center of Excellence.

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[1] The prescribing information is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212862s000lbl.pdf

[2] The August 14, 2019 TB Alliance press release is available at https://www.tballiance.org/news/fda-approves-new-treatment-highly-drug-resistant-forms-tuberculosis