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Made-in-India drug Pretomanid has potential to ensure TB elimination by 2025

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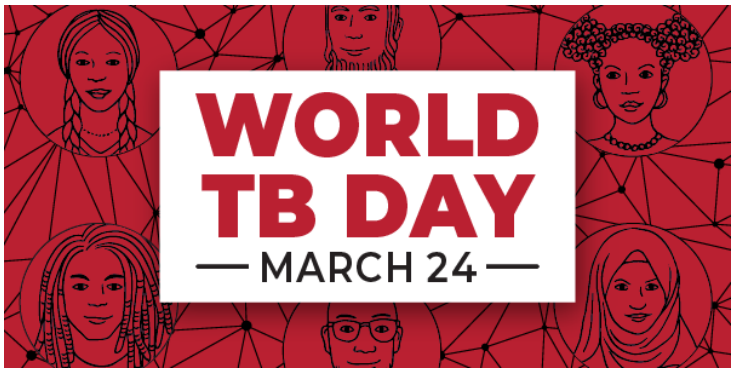
TB Alliance committed to accessibility of TB therapy in India



March 24, marks World Tuberculosis (TB) Day and TB Alliance, a global not-for-profit organization, is joining with partners around the globe to raise awareness of one of the world's oldest diseases.

In July 2020, the Drug Controller General of India (DCGI) had approved the TB drug pretomanid (developed specifically for certain drug-resistant forms of the disease) for conditional access under the National Tuberculosis Elimination Program (NTEP), making India the second country in the world to provide regulatory approval for this product.

Pretomanid is a 'made in India' product used as part of a six-month treatment regimen with reported efficacy of 90%; and has potential to contribute to India's 'TB Elimination programme by 2025.'

A government-led study of the regimen in India called mBPaL commenced in October 2021 and is now enrolling patients at three sites out of a planned 11. It is scheduled to reach its primary completion in 2023 after enrolling 400 patients.BPaL regimen combines the antibiotics bedaquiline (B), pretomanid (Pa) and linezolid (L).

To date, 17 countries or regulatory bodies, including India, have approved pretomanid as part of the BPaL regimen for the treatment of patients with highly drug-resistant forms of TB. Regulatory applications have been submitted to another 13 countries and counting by Viatris, TB Alliance's global commercialization partner for pretomanid as part of the regimen. Viatris is joined by Macleods, Lupin, and Hongqi Pharma in holding licenses for pretomanid in countries with high TB burdens.