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Mylan receives DCGI approval for TB drug pretomanid

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India becomes the worldâ??s second country to gain approval for pretomanid



Mylan, a global pharmaceutical company recently announced that the Drug Controller General of India (DCGI) has approved the anti-tuberculosis drug pretomanid for conditional access under the National Tuberculosis Elimination Program (NTEP) program, making India the second country in the world to provide regulatory approval for this product.

Pretomanid has been approved as part of a three-drug, a six-month all-oral regimen consisting of bedaquiline, pretomanid, and linezolid, collectively referred to as “BPaL” for the treatment of adult patients with pulmonary extensively drug-resistant TB (XDR-TB), treatment intolerant or non-responsive multidrug-resistant TB (MDR-TB).

Through the approval from DCGI, Mylan will initially make it's pretomanid available in India through a donation of 400 treatment courses to the Government’s National Tuberculosis Elimination Program (NTEP), which provides free, high-quality anti-tubercular drugs and care across the country to ensure that the treatment is accessible to patients who need it the most. The company also will provide commercial access to NTEP of US $364 for a six-month treatment course and will be manufacturing its pretomanid product both for domestic and global supply in India.

Mylan President Rajiv Malik said, “Mylan offers one of the world’s leading infectious disease portfolios and the approval of pretomanid in India further supports our global commitment to transform the TB treatment landscape through greater access and affordability. It also demonstrates the power of innovative partnerships, like the one we’re proud to have with TB Alliance, in expanding the availability of new medicines for patients. To date, Mylan and TB Alliance have secured approvals for pretomanid in two countries. As important, and thanks to DCGI’s continued focus on the treatment of TB even amidst the evolving COVID-19 pandemic, we achieved the approval in India with record speed. We look forward to continuing our journey to ensure the availability of treatment for those who most need it in high-burden countries globally.”