

Effectiveness of BPaL regimen for highly drug-resistant TB brings new hope for India

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TB Alliance's ZeNix trial in South Africa and Eastern Europe sought to optimize the 6-month treatment regimen with reduced exposure to the drug linezolid



The results of ZeNix, a Phase 3 clinical trial that took place in 11 sites across Georgia, Moldova, Russia, and South Africa, has revealed that the BPaL treatment remains effective against highly drug-resistant strains of tuberculosis (TB) with either reduced dosage or duration of the linezolid component of the regimen.

Simultaneously, with the maintenance of efficacy, there was a decrease in linezolid associated side effects. The results from the trial, which was led by TB Alliance, a non-profit TB drug developer, were announced ahead of an oral abstract presentation next week at the 11th IAS Conference on HIV Science, on July 15th.

The BPaL regimen—which combines the antibiotics bedaquiline (B), pretomanid (Pa) and linezolid (L)—received its first regulatory approval in August 2019 for use against highly drug-resistant strains of TB. Historically, treatment would take 18 months or longer, with reported global success rates averaging 43%.

This Phase 3 clinical trial shows how TB Alliance's new six-month, three-drug treatment for highly drug-resistant TB can be administered with reducing the dosing of the drug linezolid. This regimen reduces the treatment time for highly drug-resistant forms of TB from 18 months or longer to a six month duration.

India has the leading number of TB cases globally, accounting for more than 1 in 4 of all cases of active TB disease, including approximately 120,000 cases of drug-resistant forms of TB.

Prime Minister Narendra Modi has set an ambitious goal of TB eradication in India by 2025, ahead of the 2030 target of the Sustainable Development Goals. This bold commitment may face headwinds in the context of the unforeseen challenges posed by COVID-19, as well as the low success rates of current DR-TB treatments, which limit the potential of expanding TB services.

Mel Spigelman, M.D., President and CEO of TB Alliance, said, “We now have evidence that the BPaL regimen can be optimized to make it even easier to use. Until recently, patients with highly drug-resistant TB had to suffer through a combination of as many as eight antibiotics, some involving daily injections, for 18 months or longer.”