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ASIA EDITION

# TB Alliance announces EC authorisation of new treatment for DR-TB

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**The new drug was authorized as part of a three-drug, six-month, all-oral regimen**

Pretomanid, a novel compound developed by the non-profit organization TB Alliance, has been granted a conditional marketing authorization by the European Commission (EC) for treating highly drug-resistant forms of pulmonary tuberculosis (TB).

The new drug was authorized as part of a three-drug, six-month, all-oral regimen for the treatment of adults with extensively drug-resistant TB (XDR-TB) or multidrug-resistant TB (MDR-TB) who are treatment-intolerant or non-responsive.

The combination treatment of bedaquiline, pretomanid and linezolid – collectively referred to as the BPaL regimen – was studied in the pivotal trial entitled Nix-TB. The multicenter, open-label trial enrolled 109 adults across three sites in South Africa with XDR-TB as well as treatment-intolerant or non-responsive MDR-TB.

Pretomanid is a new chemical entity and a member of a class of compounds known as nitroimidazooxazines. Pretomanid has now received authorization as an oral tablet formulation as part of the BPaL regimen for the treatment of highly drug-resistant forms of pulmonary TB. It is now indicated for use in a limited and specific population of patients.

The most common side effects noted with the BPaL regimen are peripheral neuropathy, nausea, anaemia, vomiting, headache, dyspepsia, acne, decreased appetite, increased transaminases and gamma glutamyl transpeptidase, rash, pruritus, abdominal pain, musculoskeletal pain, and increased amylase. TB Alliance's exclusive commercialization partner in Europe is Mylan, a global pharmaceutical company, which will market pretomanid as part of the BPaL regimen.