

TB Alliance, Mylan to commercialize pretomanid to treat TB

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Non-profit drug developer, TB Alliance, and pharmaceutical company, Mylan N.V. have announced a global collaboration to make the experimental drug pretomanid accessible for use in two investigational drug regimens for pulmonary tuberculosis (TB).

Pretomanid is a new chemical entity and a member of a class of compounds known as nitroimidazooxazines. TB Alliance began preclinical development of pretomanid in 2002, and it has since studied pretomanid in 20 clinical trials alone or in combination with other anti-TB drugs. Pretomanid has been administered in a clinical trial setting to more than 1,200 people in 14 countries.

The two pretomanid-based regimens under development include: (i) For XDR-TB and MDR-TB that is treatment-intolerant or non-responsive: All oral, six- to nine-month treatment regimen consisting of bedaquiline, pretomanid and linezolid (BPaL regimen); (ii) For DS-TB and MDR-TB: All oral, four- and six-month treatments, respectively, consisting of bedaquiline, pretomanid, moxifloxacin and pyrazinamide (BPaMZ regimen)

As part of the BPaL regimen, TB Alliance has granted a license to Mylan to manufacture and commercialize pretomanid, pending regulatory approval, for XDR-TB and treatment-intolerant or non-responsive MDR-TB.

As part of the BPaMZ regimen, TB Alliance has licensed pretomanid to Mylan for DS- and MDR-TB, and has granted a sublicense for bedaquiline to Mylan, for its development and commercialization for use in DS-TB only, under its license agreement with Janssen Pharmaceutica N.V.