Pretomanid as part of the BPaL Regimen

Photo: TB Alliance

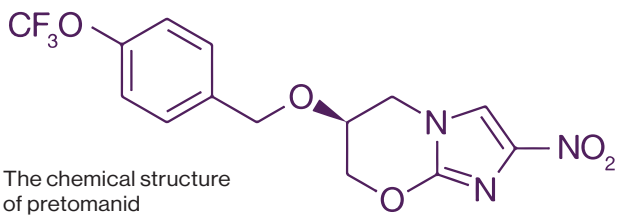
Pretomanid, a compound developed by the non-profit organization TB Alliance, is part of a three-drug, six month, all-oral regimen for the treatment of people with highly drug-resistant tuberculosis (DR-TB). The combination treatment of bedaquiline, pretomanid and linezolid is known as the BPaL regimen.

About Pretomanid

Pretomanid is a new chemical entity and a member of a class of compounds known as nitroimidazooxazines. Novel compounds are important in pursuing new TB treatments because resistance to drugs and drug classes currently used to treat TB is increasingly widespread.

During early development, pretomanid was referred to as PA-824. Pretomanid was developed by TB Alliance as an oral tablet formulation for the treatment of TB in combination with other anti-TB agents.

Today, more than 40 countries have procured more than 4,000 pretomanid treatment courses.



The chemical structure of pretomanid

About the BPaL Regimen

BPaL was first studied in TB Alliance's Nix-TB trial, which enrolled people with extensively drug-resistant TB (XDR-TB) as well as treatment-intolerant or non-responsive multidrug-resistant TB (MDR-TB). Nix-TB data have demonstrated a favorable outcome in 90 percent of people after six months of treatment with BPaL and six months of post-treatment follow-up.[1] For two patients, treatment was extended to nine months.[1] Pretomanid has been clinically studied in more than 1,100 people who participated in 19 clinical trials evaluating the drug's safety and efficacy.[2] Pretomanid has been clinically studied in 14 countries.

Prior to the introduction of BPaL, treatment of highly DR-TB was lengthy and complex. Most XDR-TB patients took a combination of up to eight antibiotics, some involving daily injections, for 18 months or longer.[3] Prior to recent introduction of new drugs for drug-resistant TB, the World Health Organization (WHO) reported estimates for treatment success rates of XDR-TB therapy at approximately 43 percent and about 57 percent for MDR-TB therapy.[4]

TB Alliance

Pretomanid has been:

- Evaluated over **18+** years
- Approved by **18** regulatory authorities
- Tested in **19** clinical trials
- Procured by **40+** countries
- Administered to **1,100+** clinical trial participants
- Prequalified by **WHO**

New WHO Guidelines on DR-TB Expand Use of Pretomanid/BPaL

The WHO recently announced an update to its guidelines for treating DR-TB, allowing for almost all DR-TB patients to be treated programmatically with either BPaL or BPaLM (BPaL + moxifloxacin) and increasing the target population for BPaL-based regimens to as many as 500,000 people each year.

Data from TB Alliance clinical trials have supported the approval and expanded use of BPaL

NiXTB

Assessed six months of BPaL for treating people with XDR-TB or treatment-intolerant/ non-responsive MDR-TB

A favorable outcome was reported in 90 percent of patients after six months of treatment and six months of post-treatment follow-up.

ZeNix

Assessed six months of BPaL for treating people with XDR-TB, pre-XDR-TB or treatment-intolerant/non-responsive MDR-TB

BPaL treatment remained effective against highly drug-resistant strains of TB with reduced dosage and/or duration of the linezolid component of the regimen. A decrease in linezolid-associated side effects accompanied the reduced dosage and/or duration.

For more information, please visit **www.tballiance.org.za**

REFERENCES

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4. World Health Organization (WHO). Global TB Report 2020.

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