Pretomanid Regimen Updates

Mel Spigelman
SHA Mid-year Webinar
June 23, 2022
Nix-TB Results

New England Journal of Medicine, March 2020

PARTICIPANTS

109 enrolled
71 with XDR-TB
65%

38 with TI/NR* MDR-TB
34%

RESULTS

90% had favorable outcomes

XDR-TB
89%
79-95 (95% CI)

TI/NR* MDR-TB
92%
79-98 (95% CI)

*Treatment-intolerant or non-responsive MDR-TB
Using definition of XDR-TB prior to 2020
Lightening the Load for Patients with Highly Drug-Resistant TB

**Historic Treatment Efforts**
14,000+ Pills, 18 Months or Longer, ~30% success

**The BPaL Regimen**
<750 Pills, 6 Months, ~90% success
Pretomanid

• Pretomanid is the first new drug to be approved by the U.S. FDA for drug-resistant TB not based on a surrogate endpoint

• First drug approved for treatment of DR-TB as part of a specific regimen
  – BPaL regimen (bedaquiline, pretomanid, linezolid), three-drug, all-oral, six-month regimen studied in the Nix-TB clinical trial

BPaL Evidence from Clinical and Preclinical Studies

Data presented to WHO Guideline Development Group

- Preclinical testicular toxicology data
- Male hormonal changes during clinical trials
- Paternity Survey

---

WHO Rapid Communication: Key Changes to treatment of DR-TB

- “The 6-month BPaLM regimen, comprising bedaquiline, pretomanid, linezolid (600 mg) and moxifloxacin, may be used programmatically in place of 9-month or longer (>18 months) regimens…” (p.5)

- “This regimen may be used without moxifloxacin (BPaL) in the case of documented resistance to fluoroquinolones (in patients with pre-XDR-TB)…” (p.5)

- “New data on the safety of pretomanid based on hormone evaluations in four clinical trials and a paternity survey were also assessed; these data have largely alleviated previous concerns on reproductive toxicities…” (p.4)
TB Alliance Donors
Thank you!