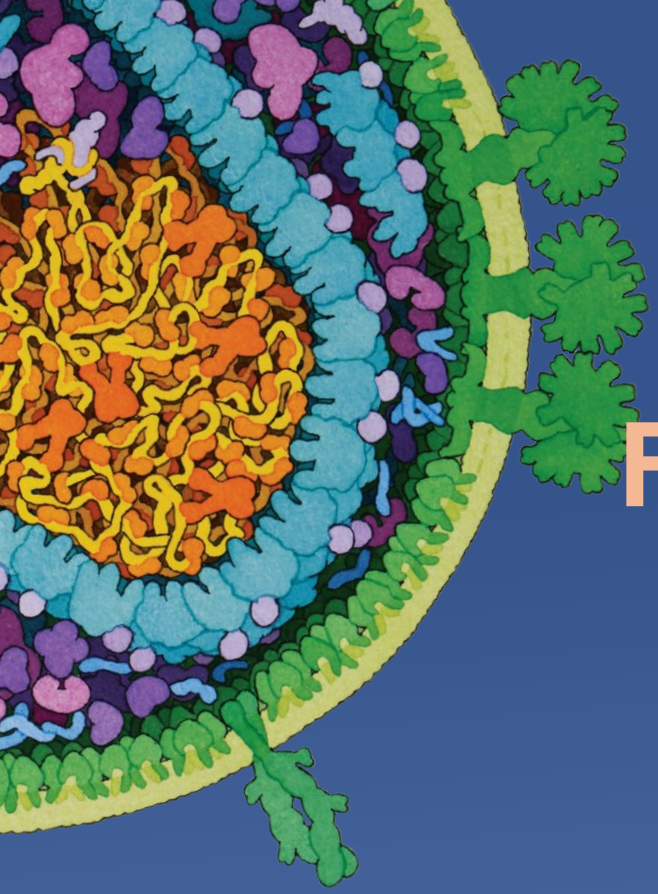

SCIENCE SPOTLIGHT™

FINAL RESULTS OF THE NIX-TB CLINICAL STUDY OF BPaL REGIMEN FOR HIGHLY RESISTANT TUBERCULOSIS

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Disclosure: None

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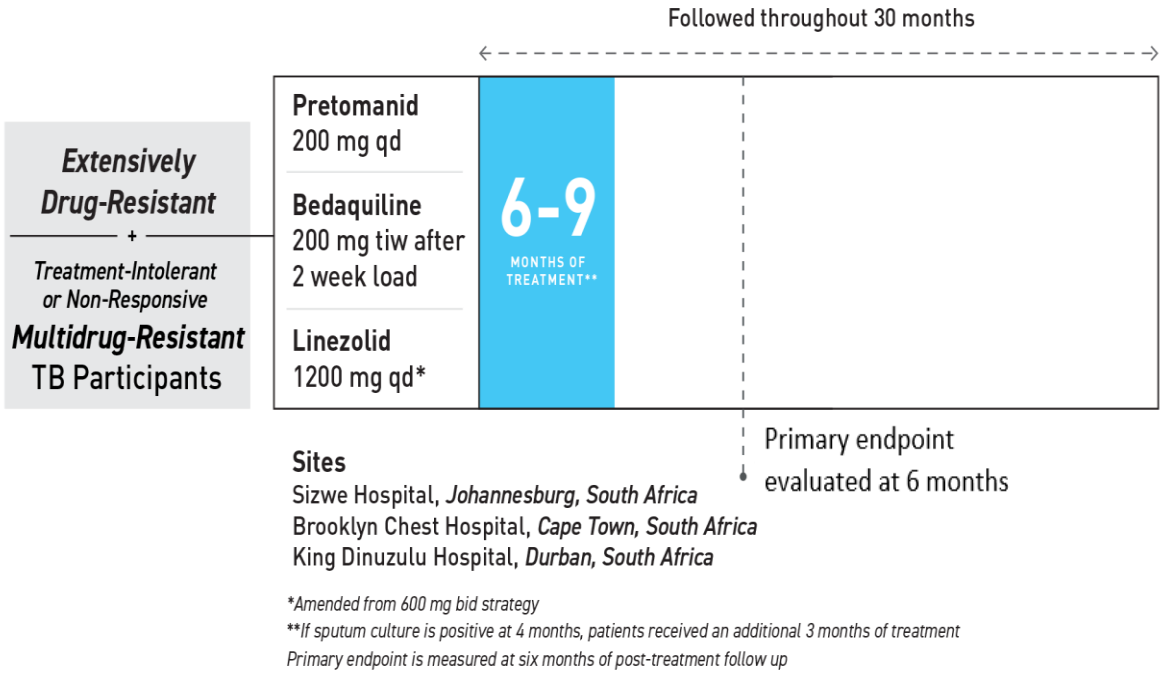
Methods

NixTB

Phase 3 Trial in XDR-TB*



- Primary and secondary endpoint = bacteriologic or clinical failure or relapse at 6- and 24-months post-treatment respectively
- Success of trial - lower bound of 95% CI > 50% favorable rate
- Peripheral neuropathy associated with linezolid was assessed serially with standard symptoms rated from none (0) to worst (10) using the Brief Peripheral Neuropathy Symptom questionnaire (BPNS)
- Explore the fate of those participants with no neuropathy symptoms at baseline who completed treatment i.e.
  - Maximum score post baseline
  - Score at end of the study (24 months)

***pre-2021 XDR definition**

Results - Efficacy

- 109 participants (65% XDR-TB, 35% MDR-TB; 51% HIV+) were enrolled and comprised the ITT population (MITT population = 107)
- All surviving participants, except 1 withdrawal, completed the full course of therapy
- At the primary endpoint six months after treatment, as previously reported, there were 98 with favorable outcomes (90% ITT, 92% mITT)
- After the primary endpoint one participant relapsed 15 months after treatment and one was lost to follow up
- Favorable outcomes 24 months post completion of treatment were sustained (88% ITT, 91% mITT) independent of sex or HIV status.

Results - Peripheral Neuropathy

Linezolid (LZD)		600mg BD (n = 44)	1200mg QD (n = 65)	Total (n = 109)
Participants who completed treatment	n	40	63	103
Participants received full uninterrupted 26 weeks of LZD at any dose	n	10	27	37
Participants received full uninterrupted 26 weeks of LZD at 1200mg daily	n	4	12	16
LZD duration in treatment completers	Mean (weeks)			23,3

Baseline	After Baseline		Month 24 After End-of-Treatment			
Pain, aching and burning			None	Mild/Mod	Severe	N/A
None: 84	Always None:	27	27	0	0	0
(Mild/Mod: 15)	Max. Mild/Mod:	34	29	3	0	2
(Severe: 1)	Max. Severe:	23	13	7	1	2
		84	69	10	1	4
			82%	12%	1%	5%

Conclusion

- Results of this simplified, shortened all oral regimen for highly drug resistant TB show sustained high efficacy through 2-year follow-up from end of treatment
- Peripheral neuropathy from linezolid was common, but manageable, and symptoms improved over 24 months of follow-up
- A follow-on trial, ZeNix, that investigates the optimal dose and duration of linezolid in the BPaL regimen, has completed enrollment
- Implementation trials using BPaL are about to begin

Thank you

Questions?

Email: *phowell@witshealth.co.za*

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