

TB Alliance launches 'Nix-TB' clinical trial to test new XDR-TB treatment

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TB Alliance and its partners announced the start of a clinical trial of a new regimen to treat extensively drug-resistant tuberculosis (XDR-TB.) It is the first study to test an all-oral drug regimen, comprised of drugs with minimal pre-existing resistance, that has the potential to shorten, simplify, and improve treatment for XDR-TB.

"XDR-TB is an absolute devastation to patients, their families, and communities. The study is the first to test a novel and potentially transformative regimen for XDR-TB, which could be a valuable tool as we battle this problem on the front lines in South Africa and around the world," said Francesca Conradie, MD, the Principal Investigator of the Nix-TB (New Investigational Drugs for XDR-TB) trial and Clinical Advisor at Sizwe Hospital, in Johannesburg, South Africa. "The strategic emphasis by our National Department of Health on clinical research for drug-resistant TB coupled with rigorous regulatory framework has enabled this trial to be conducted in South Africa.

XDR-TB is a strain of tuberculosis, air-borne and infectious, that has resulted from progressive antibiotic resistance and is resistant to four commonly used anti-TB drugs. XDR-TB has been reported in 100 countries. It is complicated and expensive to treat and results in high rates of death. Today, there are no regulatory-approved XDR-TB treatments.

Currently, healthcare providers treat XDR-TB by individualizing [treatment](#) regimens, frequently using antibiotics not normally used for TB as well as toxic medicines not meant for the long treatment duration that TB requires. People with XDR-TB can be on treatment for two years or longer, with thousands of pills and injections, extensive side effects, and little success. In a [recent review](#) of the experience in South Africa, after two years of treatment only a fraction of people—16 percent—with XDR-TB were cured.

Resistance to available antibiotics has plagued efforts to combat the TB pandemic, creating distinct drug-resistant strains of the bacteria such as multi-drug resistant TB (MDR-TB) and XDR-TB and rendering current treatments inadequate. However, the three drugs that comprise the treatment being tested in Nix-TB have novel mechanisms of action. The three-drug regimen consists of bedaquiline (B), which received conditional regulatory approval in several high-TB disease burden countries; the novel antibacterial drug compound pretomanid (Pa), which is being tested in multiple clinical trials; and linezolid, an oxazolidinone, which has been used off-label to treat TB.

If the regimen tested in Nix-TB is successful and safe in XDR-TB, that will pave the way for expanding the study, testing its potential to use in people with MDR-TB and then potentially in people with drug-sensitive TB. Having a regimen that would be usable in such a broad range of TB patients could significantly improve TB control efforts globally.

"We are testing a promising treatment for XDR-TB today, but the longer-term potential of such a regimen is even greater. We now see the possibility of a single TB regimen that can treat virtually all patients with active TB with a relatively simple and affordable regimen," said Mel Spigelman, MD, President and CEO of TB Alliance. "The launch of Nix-TB is a critical step to achieve the vision of a truly short-course, simple, affordable and well-tolerated universal treatment regimen."

Nix-TB is a partnership between TB Alliance, a not-for-profit organization with the mission of developing improved TB treatments and the sponsor of the trial; Janssen Pharmaceutica NV (Janssen), the originator company that in 2009 granted a royalty-free license to the TB Alliance for the development and commercialization of bedaquiline in the field of drug-susceptible TB; and the sites in South Africa where the study is and is

expected to be conducted (Sizwe Hospital, TASK at Brooklyn Chest Hospital, and THINK at Doris Goodwin Hospital).

The cost for the initial phase of Nix is covered by a group of long standing TB Alliance donors. The TB Alliance is starting to bring together additional funding to expand the study and the number of sites.

"The availability of new TB drugs offers the unprecedented opportunity to improve treatment for people with TB. However, the existence of individual new drugs is not enough," said TB Alliance's Spigelman. "TB must be treated in multi-drug combinations or regimens to enhance efficacy and prevent the development of resistance. Therefore, the Nix-TB trial fills a critical gap and capitalizes on the availability of novel drugs by studying them together in the most vulnerable TB population, those with XDR-TB, and in such a way that provides clear understanding of how to use the treatments to maximize their impact on the epidemic."

Provided by Burness Communications

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