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TB Alliance Launches Clinical Trial for New TB drug

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TB ALLIANCE

TB Alliance, a not-for-profit organization dedicated to finding faster-acting and affordable drug regimens to fight tuberculosis (TB) has initiated a pivotal clinical trial, SimpliciTB that will evaluate whether a new four-drug regimen can treat most types of tuberculosis (TB) including multidrug-resistant TB (MDR-TB) more quickly and effectively than currently-available treatments. The first patients have been enrolled at the National Center for Tuberculosis and Lung Disease in Tbilisi, Georgia. SimpliciTB is expected to enroll 450 people with TB, including up to 150 with MDR-TB* across at least 26 centers in 10 countries in Africa, Asia, Europe and Latin America.

SimpliciTB will test the efficacy of a four-month treatment with the BPaMZ regimen, consisting of the drugs bedaquiline, pretomanid, moxifloxacin and pyrazinamide, in people with drug-sensitive TB. Outcomes will be compared against the standard six-month treatment regimen of isoniazid, rifampicin, pyrazinamide and ethambutol (HRZE), to determine whether

BPaMZ may be able to shorten the duration of therapy for drug-sensitive TB by a third.

The trial will also assess BPaMZ's potential to treat MDR-TB in six months. Currently, treatment for drug-resistant TB is extremely complicated, expensive, and lengthy, involving a wide variety of medicines that have debilitating side-effects, injectable drugs, and are administered for nine months to two years or longer. Today, people with MDR-TB often go untreated, and of those who do receive treatment only about half are cured.

"As resistance to current TB treatments continues to grow, we need to introduce all-oral drug regimens that can treat every person with TB in six months or less, regardless of their resistance profile," said Mel Spigelman, president and CEO of TB Alliance. "If proven successful in SimpliciTB, the BPaMZ regimen would represent a major step toward this goal."

The BPaMZ regimen was previously studied in the Phase 2b study called NC-005, in which people with MDR-TB who were treated with the BPaMZ regimen cleared TB bacteria from their lungs up to three times faster than drug-sensitive TB patients treated with the standard (HRZE) treatment. NC-005 was an eight-week trial conducted at 10 sites across Uganda, South Africa and Tanzania. SimpliciTB builds on these results, testing BPaMZ over a longer duration, in more people and across more sites, and against both drug-sensitive and MDR-TB.

According to the World Health Organization's most recent Global Tuberculosis Report, there is growing resistance to available drugs, which means the disease is becoming more deadly and difficult to treat. WHO estimates that in 2016 there were 600,000 new cases with resistance to rifampicin – the most effective first-line drug—of which 490,000 had MDR-TB.

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