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GROUNDBREAKING TRIAL OF A ONE-MONTH REGIMEN TO PREVENT ALL FORMS OF TUBERCULOSIS SET TO LAUNCH

First study to evaluate bedaquiline, a game changing TB treatment drug, as a shorter, safer regimen for TB prevention

NEW YORK CITY, September 19, 2023 — In the lead up to the second United Nations (UN) High-Level Meeting on Tuberculosis, Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination (SMART4TB) announced plans to conduct a transformational multinational study of a one-month treatment regimen to prevent all forms of tuberculosis (TB), including drug-resistant TB.

BREACH-TB (**B**edaquiline **R**oll-**O**ut **E**vidence in TB Contacts and People Living with **H**IV to Prevent Tuberculosis) will test whether one month of oral bedaquiline, a potent drug that has revolutionized the treatment of drug-resistant TB, can prevent both drug-resistant (DR) and drug-susceptible (DS) TB in people exposed to either form of TB in their households and in people with HIV infection, including pregnant women and children.

“Developing a short regimen that can prevent both DR- and DS-TB infections from advancing to active TB disease will greatly simplify options for TB preventive treatment (TPT) and ensure that more people exposed to TB in high-burden countries will get and complete treatment, helping to achieve the UN’s goal of Ending the TB Epidemic by 2030,” said SMART4TB chief of party, Dr. Richard Chaisson, professor of medicine at Johns Hopkins University School of Medicine.

TB is a leading infectious killer globally, with an estimated 1.6 million deaths in 2021. In 2018, the first-ever UN High-Level Meeting on TB made ending the disease a global priority and set the target of preventing 30 million new cases between 2018 and 2022. However, less than half of the target was reached. The World Health Organization has prioritized preventive therapy as a key strategy for ending TB.

“The study design of BREACH will allow us to boldly investigate a promising preventive pan-TB regimen—meaning that household contacts, people living with HIV and other key members of TB-affected communities, will be part of a global effort to get us closer to a safe and effective preventive treatment for all,” said Dr. Payam Nahid, SMART4TB’s senior scientific advisor and professor of medicine at the University of California, San Francisco.

Preventive therapy is only successful if the person with latent TB completes the course of medication. However, people with latent TB infections don't show symptoms of the disease, making it more difficult to keep them on a long, arduous medication schedule solely for prevention. Providers know this and would prefer to offer shorter regimens as a first-line option to ensure they are fully completed. While short-course regimens for DS-TB have been available for several years, individuals exposed to DR-TB can only be treated with longer courses of unproven regimens to prevent development of TB disease.

Approved by the United States Food & Drug Administration in 2012, bedaquiline was the first new drug to be developed for TB in 40 years. It has since become a game-changer in the treatment of DR-TB. The BREACH Study will be the first to evaluate bedaquiline for TB prevention.

SMART4TB is a cooperative agreement with the United States Agency for International Development (USAID), made possible by the generosity of the American people.

"A shorter regimen that fights both drug-resistant and drug-susceptible TB would be a game-changer for those living with TB and get us closer to our shared goal of ending the epidemic by 2030. This clinical trial will lay the foundation for a remarkable innovation in our fight against TB: a single-dose, long-acting injectable medicine," said Dr. Atul Gawande, USAID assistant administrator for Global Health.

The study is being led by researchers Drs Eric Nuermberger and Sonya Krishnan at Johns Hopkins University. It is slated to begin enrollment in 2024.

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The SMART4TB Consortium brings together experts in TB tools development, implementation science, capacity strengthening, civil society engagement, and policy translation. Led by [Johns Hopkins University](#), consortium members include [Elizabeth Glaser Pediatric Aids Foundation](#), [KNCV Tuberculosis Foundation](#), [Treatment Action Group](#), and [University of California San Francisco](#).