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SMART4TB ANNOUNCES PARTNERS IN DEVELOPING GROUNDBREAKING ORAL, NON-SPUTUM-BASED MOLECULAR TESTS FOR TUBERCULOSIS

Significant investment in technology marks major advance in point-of-care testing, the highest priority diagnostic need for TB prevention and care

BALTIMORE, January 9, 2024 — Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination (SMART4TB) is excited to announce Boditech Med, Co-Diagnostics, Nuclein and Molbio Diagnostics as partners in developing oral swab-based, point-of-care molecular TB tests.

"The United States Agency for International Development's (USAID) strategic investment in diagnostics technology for TB is an area ripe for innovation," said Claudia Denkinger, head of the Division of Infectious Diseases and Tropical Medicine at University Hospital Heidelberg. "COVID-19 showed us that with the right incentives, many developers could utilize technology they were already working on to create efficient, scalable tests for different diseases. We have a similar ambition for TB, and this investment marks a vital step in the right direction."

According to the World Health Organization's 2023 Global Tuberculosis Report, 10.6 million people fell ill with tuberculosis (TB) in 2022; 3.1 million were not reported because they were either not diagnosed or were diagnosed and not linked to care. Rapid molecular TB testing through platforms such as GeneXpert and Molbio has been an important advancement for TB by providing faster, more accurate diagnoses, including the detection of drug resistance. However, these tests largely still rely on sputum samples, which can be difficult to produce, and require infrastructure that challenges their use in a range of places where people seek care. To effectively treat people in settings where they are more likely to visit, healthcare providers need a test that is fast, accurate and can be conducted in any clinical setting.

"Rapid tests at the point of care for a person with TB is a game-changer. From the perspective of people with TB, it means getting a faster diagnosis and planning for potential treatment. From the clinician's and program's perspective, rapid, point-of-care testing can reach more people and improve the entire cascade of care, from prevention through treatment to contract tracing," said Adithya Cattamanchi, chief, Division of Pulmonary Diseases and Critical Care Medicine at University of California, Irvine.

Developers were selected by a panel of 11 TB and diagnostics experts from academic institutions, the United States Agency for International Development (USAID) and prominent organizations. The developers already have point-of-care molecular platforms in pre-commercialization or commercialization phase. In this effort, SMART4TB will provide financial

and technical support to help adapt their technology to TB, and clinical support and regulatory guidance to help bring the final product to communities affected by TB.

“We’re excited about these partners because of the innovation they showed in their applications,” said Yuka Manabe, director at the Center for Innovative Diagnostics for Infectious Diseases at Johns Hopkins University School of Medicine. “We believe they have a high chance of success in bringing a test to market on an aggressive timeline and ultimately, bringing TB care close to many more people.”

This project has three development phases, from prototype to a design-locked clinically evaluated test. Partners selected for the first phase will only move to the next phase if their test meets designated standards and will be evaluated by a series of experts, including affected community members.

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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.

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