

TO: Secretary of the Expert Committee on the Selection and Use of Essential Medicines Medicines Selection, IP and Affordability (MIA)

Department of Health Products Policy and Standards (HPS)

World Health Organization

By email via emlsecretariat@who.int

March 20, 2023

Re: Letter of Strong Support for Inclusion of Pretomanid 200 mg Tablets on the World Health Organization Model List of Essential Medicines

Dear Expert Committee,

On behalf of the Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination (SMART4TB) Consortium, we are pleased to express our strong support for the Global Alliance for TB Drug Development's application for inclusion of pretomanid 200 mg tablets on the World Health Organization (WHO) Model List of Essential Medicines (EML).

According to WHO's Global TB Programme, drug-resistant TB cases are on the rise; an estimated 450,000 people worldwide fell ill with drug-resistant TB in 2021 alone. Effective, tolerable treatment is needed to cure people with TB, and stop onward transmission.

Pretomanid, <u>approved by the U.S. Food and Drug Administration</u>, is a component of the game-changing 6-month regimen for treating drug-resistant TB recommended in the 2022 update to the WHO Global TB Programme's <u>consolidated guidelines</u>. This regimen dramatically shortens treatment for TB from previous 9- to 18-month therapies, alleviating burdens on patients, providers, and programs alike. Results from the <u>TB-PRACTECAL trial</u> indicate that the regimen is not only shorter while preserving efficacy, but safer than the previous standard of care.

SMART4TB aims to transform TB prevention and care, using person-centered methods and tools. Pretomanid is a key element for achieving these goals. Including pretomanid on the EML will help make it accessible to all who need it, improving the lives of people with TB and all those who care for them. We look forward to your favorable review of this essential medicine. Please do not hesitate to contact Erica Lessem, <a href="mailto:elessem1@jh.edu">elessem1@jh.edu</a>, should you require any further information about our support for pretomanid.

Thank you in advance,

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[signatories continued on next page]



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