CIVIL SOCIETY DEMANDS AFFORDABILITY, TRANSPARENCY AND ACCOUNTABILITY FROM THE TB ALLIANCE

We are a coalition of civil society and community-based organizations committed to ensuring that communities affected by TB are engaged in and have access to the benefits of research. We interrupt this meeting to present our shared concerns and to demand transparency and accountability from the TB Alliance.

The US Food and Drug Administration approved pretomanid as part of a regimen in August, and the World Health Organization will convene a Guideline Development Group Meeting in November. Yet, the size and design of the Nix-TB trial has left many questions about pretomanid unanswered.

The TB Alliance must commit to filling the following research gaps, and to doing so expeditiously and using rigorous study designs.

- We want data to (1) confirm the safety and efficacy of pretomanid; (2) to evaluate how pretomanid compares to delamanid, a medicine from the same class; and (3) to evaluate how pretomanid-containing regimens compare to other regimens that include bedaquiline and linezolid;
- We want to know if pretomanid can be safely given to people living with HIV with low CD4 counts, including those on dolutegravir; and
- We want to know if pretomanid can be safely given to children.

The TB Alliance should support or carry out these studies, using revenue generated from the sale of its Priority Review Voucher.

In the meantime, the TB Alliance must commit to supporting operational research and other studies necessary to understand the challenges of incorporating pretomanid and the Nix-TB regimen into programmatic use. The TB Alliance must also commit to ensuring appropriate use and intensive pharmacovigilance measures outside of clinical trials, as the safety and efficacy of pretomanid have yet to be confirmed.

The TB Alliance must commit to publishing all of its research findings in the peer-reviewed literature, and to sharing them with research participants and the broader community. Results dissemination is a core principle of Good Participatory Practice, and the TB Alliance's responsibility. We note with concern that findings from the STAND trial have yet to be published. These data offer additional information about the safety and efficacy of pretomanid and should presented for public scrutiny.

In addition to committing to the conduct of additional research, intensive pharmacovigilance monitoring, and results dissemination, we urge the TB Alliance to ensure that pretomanid is equitably accessible to XDR-TB patients in need, including through an affordable low price and free compassionate use program while registrations are being prepared and/or pending.

The TB Alliance is a non-profit organization, funded through grants. The TB Alliance developed pretomanid using public and philanthropic funds. As such, pretomanid is a public good – developed for us, by us.

Despite repeated requests for transparency, the full licensing agreement between the TB Alliance and Mylan have not been made available to the public.

The public is entitled to see the terms dictating how pretomanid, which was developed by and for the public, will be made available across the world.

We again call on the TB Alliance to commit to transparency, and to quit behaving worse than pharma, by making public the full terms of its agreements with Mylan and Macleods.

We want rigorous research, informed by communities.

We want data transparency.

We want pharmacovigilance monitoring.

We want a low affordable price, lower than the $364 per six-month course offered to GDF, based on the cost of production, and equitable access to pretomanid for XDR-TB patients in need.

We want free drug for compassionate use.

We want rapid registration in high-burden countries.

We want the licensing agreements to be made public.

DR-TB STAT

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ZERO child deaths from DR-TB
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