TB Alliance

New York
80 Pine Street, 20th fl.
New York, NY 10005
+1 212 227 7540

Pretoria
Boardwalk Office Park,
Block 1/Suite 5,
107 Haymeadow Street,
Faerie Glen, Pretoria 0043,
South Africa
+27 12 991 6328

www.tballiance.org

June 2025

Subject: Your letter of April 15, 2025, regarding certain Eurasian patent applications for pretomanid.

Dear ECAT team,

Thank you for your letter and for your continued engagement on issues of access to TB treatment. We are grateful for your appreciation of TB Alliance's work in combatting TB and respect the perspectives you and your partner organizations shared in your communication.

As discussed in our written response from May 2024 and in our August 2024 call, we reaffirm that as a nonprofit product development partnership, TB Alliance's aim is not to enforce exclusivity on products developed by us or to make or maximize profits from our intellectual property. Instead, our patent and licensing strategy exists to support responsible, sustainable access to quality-assured TB treatment. While we appreciate that we are not a regulator and it is the role of regulatory agencies to ensure quality of marketed products, our patenting and licensing strategy acts are a preventative mechanism particularly in resource-limited settings where quality standards and regulatory oversight varies. Additionally, our licensees must follow rigorous standards of stewardship and are required to not commercialize or market pretomanid in any indication or manner that is inconsistent with approved label or WHO guidelines, preventing potential misuse and development of resistance. Thus, our licensing strategy ensures consistency of quality and usage irrespective of geography.

Crucially, all patents related to pretomanid are licensed on a royalty-free basis for developing countries. We do not issue exclusive licenses in those settings and have granted non-exclusive rights to multiple manufacturers to stimulate healthy competition and safeguard supply security. We draw your attention to the recent price reduction by ~25% to $169/treatment due to market entry of our third licensee which translates into overall 54% price reduction for pretomanid from initial launch in late 2019, despite a starting price which was 60-80% lower than the first access price for bedaquiline and delamanid. We are confident that further competitive tenders and increasing volumes – both of which are expected – will continue to drive pretomanid prices down owing to robust generic competition that we have enabled through our licensing strategy.

We would also like to highlight that in all countries in the jurisdiction of the Eurasian patent office, where the patent EA 201890614 referenced in your communication is filed, pretomanid has been licensed non-exclusively except in Russia. All TB Alliance licensees are able to service all countries

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in the Eurasian region except Russia where Viatris is working exclusively with a local distributor to supply pretomanid.

Regarding your point about enabling local manufacturers in high burden countries, we would like to point out that we have licensed two such manufacturers – Hongqi in China and Remington in Pakistan. Hongqi has recently received regulatory approval in China and has introduced pretomanid under an access program while awaiting price approval.

However, as highlighted in our previous communication, we remain open to further licensees that meet quality and stewardship criteria – and welcome referrals to any high-quality producers interested in manufacturing pretomanid. Please forward the names of any potential licensees whom you know wish to manufacture pretomanid.

While we believe that our very unique licensing and patenting strategy is working and is creating the opposite effect than increasing prices or preventing competition, please send us the analyses to which you refer. In the spirit of collaboration and open dialogue, and as we advance efforts to scale access to pretomanid, develop pediatric pretomanid, and next-generation TB treatments as referenced in your letter, we welcome all constructive suggestions.

Warm regards,

Stephanie Seidel
Senior Manager, External Affairs