

14 March 2013

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USA
Email: Janssenrnd@its.jnj.com

Dear Dr. Stoffels,

We would like to congratulate you and everyone at Janssen on the U.S. Food and Drug Administration's approval of bedaquiline in December 2012. We look forward to this new drug being made available to people with drug resistant tuberculosis (DR-TB). As you begin registration in other countries and roll out of bedaquiline where approved, we ask you to determine a fair and affordable price, essential for timely approval and appropriate domestic and global access to the best possible therapeutic options for people with DR-TB.

Here in the United States, for example, states and localities are facing ongoing budget austerity which is making it harder for them to afford costly treatments for drug-resistant tuberculosis; thus, it is essential for Janssen, when pricing bedaquiline for the domestic market, to recognize these constraints by charging a price low enough for these jurisdictions to afford.

Fair and affordable pricing means concessional pricing in both the low- and middle-income countries that disproportionately bear the burden of TB, and affordable pricing in low-incidence settings such as the United States where TB programs receive few resources.

We also ask that you implement a patient assistance program for bedaquiline here, in the United States, and offer co-pay subsidies.

Finally, we request that Janssen expedite your work to conduct further research necessary to determine bedaquiline's safety and optimal use including: the FDA-required phase III trial, a follow up study in persons taking ARVs if an inadequate number of people with HIV are enrolled in the phase III trial, a DDI study with delamanid, pediatric studies in children with MDR-TB with and without HIV, and studies to inform the use of bedaquiline in people who use drugs, including studies of drug-drug interactions between bedaquiline with buprenorphine and with methadone and for those coinfecting with hepatitis B virus or hepatitis C virus.

TAG and the global TB Community Advisory Board (TB CAB) look forward to discussing these issues further with you and the Janssen bedaquiline team. Please do feel free to call me at +1 212 253 7922 or email me at mark.harrington@treatmentactiongroup.org at any time.

Best regards,

Polly Clayden, United Kingdom
Alberto Colorado, United States
Colleen Daniels, United States
Nathan Geffen, South Africa
Denis Godlevskiy, Russian Federation
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for the Global Tuberculosis Community Advisory Board (TB CAB)