To: Paul Stoffels M.D., Chief Scientific Officer and Worldwide Chairman
Ross Underwood, Global Commercial Access Leader
Chrispin Kambili, Global Medical Affairs Leader
Tine de Marez, Project Management Office Leader
Pharmaceuticals, Johnson & Johnson
One Johnson & Johnson Plaza
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Cc: Lucica Ditiu, Executive Director, Stop TB Partnership
Brenda Waning, Chief, Global Drug Facility, Stop TB Partnership
Cheri Vincent, Chief, Infectious Disease Division, USAID
Greg Perry, Executive Director, Medicines Patent Pool
Precious Matsoso, Director-General, National Department of Health, South Africa

19 September 2016

OPEN LETTER RE: Requests to improve affordability and availability of bedaquiline

Dear Dr. Stoffels and colleagues,

We write to you as a group of advocates, clinicians, and researchers to underscore the importance of the accessibility of bedaquiline (Sirturo) for treating multidrug-resistant tuberculosis (MDR-TB). As you know, bedaquiline is one of very few new tools we have in the armament for treating MDR-TB, and offers great hope for people with MDR-TB for whom a regimen cannot otherwise be constructed. However, programmatic uptake of bedaquiline remains far below what it must be to impact the MDR-TB epidemic. **We urge you to improve access by making bedaquiline immediately available via the Global Drug Facility (GDF) at the single, flat price of USD$52.8 per treatment course to all middle-income countries, and to low-income countries, when the donation program ceases.**

We acknowledge and appreciate the important steps Janssen has made to date to develop bedaquiline and make it more accessible, such as making bedaquiline available through the GDF to a select list of countries, providing bedaquiline for free to all Global Fund-eligible countries via a partnership with USAID, and proactively registering the drug with stringent regulatory authorities and high MDR-TB burden countries. We also acknowledge the significant tax breaks and good press that such a donation provides, and the valuable priority review voucher (PRV) Janssen received for its development of bedaquiline.

However, nearly four years since bedaquiline's approval by the U.S. Food and Drug Administration, and two and a half years since its entry into the GDF catalogue, we remain troubled by the lack of availability and consequent underuse of bedaquiline. As of 9

September 2016, only 4,663 orders of bedaquiline have been placed through the GDF. An additional nearly 5,000 courses have been used in Russia and South Africa, countries that are not eligible for the donation program. Given estimates that 30–67% of people who develop MDR-TB each year would be eligible to receive bedaquiline based on World Health Organization (WHO) guidelines,[i] this is far below the 144,000–321,600 courses needed to treat new cases alone. Several factors contribute to the low levels of uptake currently, but there are key high-impact changes Janssen can and must make that will radically improve bedaquiline's availability. We urge Janssen to:

1) **Lower the price of bedaquiline to $52.8 per course for all middle- and low-income countries when the donation program ends.** While bedaquiline is currently available for free for Global Fund-eligible countries, non-eligible countries face a complicated and often prohibitive pricing structure. For the countries covered under the initial 2014 GDF agreement, middle-income countries are expected to pay $3,000 per course. But many countries are interested in procuring bedaquiline and are not covered by either the donation program or GDF pricing structure, and are being asked to pay wildly divergent prices from $700 to $30,000 per course. This is much higher than the target price of $500 for an entire MDR-TB regimen.[ii] Rigorous cost of goods modeling has shown that bedaquiline could be produced for just $8.80–16.40 per month.[iii] We therefore ask you to lower the price of bedaquiline to $52.8 per six-month treatment course. If you claim this is not feasible, we ask you to work with GDF to find creative solutions to develop a realistic and still affordable counter figure or to consider voluntary licensing. We do acknowledge that achieving low prices may require higher volumes of procurement, but without a dramatic price reduction for countries not eligible for the donation program, we are trapped in a vicious cycle where pricing prohibits the purchase of larger volumes of bedaquiline, while the small volumes being procured perpetuate the rationale for a higher price. Janssen could break this cycle and make bedaquiline more viable for widespread use by lowering bedaquiline's price.

2) **Expand eligibility criteria for accessing bedaquiline through the GDF to include all countries.** Bedaquiline's availability is currently limited to only a certain set of countries, and the donation program announced in 2015 was further restricted to only Global Fund-eligible countries. Several countries with high MDR-TB burdens are no longer Global Fund-eligible or are in transition, and are excluded from the existing GDF-Janssen agreement, leaving them without a clear mechanism or price structure for procuring bedaquiline. GDF plays a hugely important role in consolidating demand and streamlining procurement for TB products; providing technical assistance to countries on procurement, forecasting, and regulatory issues; and easing transaction costs, reducing administrative burden, and improving volumes and market stability for suppliers. Allowing all countries to procure bedaquiline through the GDF would make their procurement processes more efficient and cost-effective, as well as reduce effort and expense on Janssen's end.

We look forward to your positive response to the above demands, which we request by 3 October 2016, and which can be directed to Wim Vandevelde at wim@eatg.org.

Respectfully submitted,
Access to Rights and Knowledge Foundation (ARK), India
DR-TB Scale-up Treatment Action Team (DR-TB STAT), Global
Global TB Community Advisory Board (TB CAB), Global
Nagaland Users' Network (NUN), India

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[i] Bonnet M, Bastard M, du Cros P, et al. Identification of patients who could benefit from bedaquiline or delamanid: a multisite MDR-TB cohort study. Int J Tuberc Lung Dis. 2016 Feb;20(2):177-86. doi: 10.5588/ijtld.15.0962.

[ii] Médecins Sans Frontières Access Campaign. Ready, Set, Slow Down. Geneva: Médecins Sans Frontières; 2015. https://www.doctorswithoutborders.org/sites/usa/files/attachments/msf_issuebrief_drtb_readysetslowdown.pdf

[iii] Gotham G et al. Target prices for novel treatments for drug-resistant tuberculosis. 15th European AIDS Conference (EACS). 21-24 October 2015. Barcelona, Spain. Oral abstract 351.