To: Paul Stoffels, Worldwide Chairman, Pharmaceuticals
CC: Ross Underwood, Global Commercial Access Leader
Myriam Haxaire-Theeuwes, Compound Development Team Leader
Chrispin Kambili, Global Medical Affairs Leader-Infectious Diseases
Tine de Marez, PMO Therapeutic Area Lead
Janssen Pharmaceuticals Companies of Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933, USA

[see additional CC list at end of letter]

10 September 2014

Open letter: Reducing the price of bedaquiline

Dear Dr. Stoffels,

We congratulate Janssen on the development of bedaquiline (Sirturo) for the treatment of drug-resistant tuberculosis (DR-TB). Bedaquiline, the first new TB drug from a new drug class to receive approval in over 40 years, is critically important for people with DR-TB with limited treatment options. Yet bedaquiline is not accessible to the patients and TB programs who need it. Once registration barriers are overcome, Janssen's prohibitive pricing and patenting of the drug will become the major barrier to access. Janssen's parent company, Johnson & Johnson, states clearly in its credo that the company's "first responsibility is to the doctors, nurses and patients," and the importance of "reasonable prices." **We appeal to Janssen to uphold this credo by lowering bedaquiline's price for all non-high-income countries.**

Bedaquiline's current tiered pricing structure poses a significant barrier to uptake of the drug, especially for developing countries not considered low-income economies. Tiered pricing presents a special challenge in TB by fragmenting demand and complicating purchasing negotiations, countering the TB community's efforts to create a more appealing market for industry by pooling demand and procurement through institutions like the Global Drug Facility. More generally, tiered pricing has been recognized as an ineffective way to promote access to medicines.[1] Tiered pricing based on country income is arbitrary, ignoring disparities within countries with respect to actors' ability and willingness to pay for medicines.

The pricing of a six-month course of bedaquiline at US$30,000, US$3,000 and US$900 for high-, middle- and low-income countries, respectively, is much too high for national TB programs and treatment providers, which have limited budgets and are already struggling to scale-up DR-TB regimens. And in countries where DR-TB

[1] William New, "Concerns Raised To Global Fund Over Panel On Tiered Medicines Pricing," Intellectual Property Watch. December 10, 2013. Available from: http://www.ip-watch.org/2013/12/10/concerns-raised-to-global-fund-over-panel-on-tiered-medicines-pricing/. (Accessed 14 August 2014)

treatment is not freely provided, this drug is out of reach of patients paying out of pocket. Bedaquiline's high price also reduces the reach of donor funding, which could otherwise support treatment for more patients, and more investments in health systems and programs.

The high price of bedaquiline is a challenge particularly for middle-income countries, which shoulder the majority of the TB burden, and often have low DR-TB budgets similar to those of low-income countries.[2] The total cost of a DR-TB regimen—usually between $1,670-$5,000 without new drugs—impacts the necessary scale-up of treatment in these settings.

The effect of one drug costing $3,000 when added into a multi-drug regimen may result in TB programs rationing bedaquiline for the most severe cases or discontinuing use of other important drugs. Such sub-optimal use of bedaquiline risks endangering patients and communities, and reducing the effectiveness of the drug. Additionally, since Janssen requires programs administering bedaquiline to report data into their registry, these programs shoulder large pharmacovigilance costs to help Janssen gather key data to fill gaps from clinical trials about the drug's safety to meet the conditions of regulatory approval.

Furthermore, we note that much of Janssen's investments in bedaquiline have already been offset by significant funding from public institutions (such as the U.S. National Institute of Allergy and Infectious Disease to support key research on bedaquiline's drug-drug interactions), the potentially profitable priority review voucher from the U.S. Food and Drug Administration (FDA), and the government of France. A priority review voucher was just sold for $67 million dollars.[3] Janssen is also benefitting from the U.S. government Orphan Drug Tax Credit, equivalent to 50% of the costs of clinical trials, and seven years of additional marketing exclusivity which the Orphan Drug Act provides.[4]

We are aware that Janssen is negotiating independently with several high-burden, middle-income countries to allow them to access the lowest-tier price; we applaud this flexibility and promotion of access. We ask you to formalize this policy for all middle-income countries by simply removing the middle pricing tier, thereby allowing all non-high-income countries to access a lower price and avoid individual negotiations. We call on Janssen to ensure that the policy of removing the middle

---

[2]Floyd K, Fitzpatrick C, Pantoja A, Raviglione M. Domestic and donor financing for tuberculosis care and control in low-income and middle-income countries: an analysis of trends, 2002-11, and requirements to meet 2015 targets. Lancet Glob Health. 2013 Aug;1(2):e105–15. doi: 10.1016/S2214-109X(13)70032-9.

[3] Fierce Biotech, "BioMarin Sells Priority Review Voucher for $67.5 Million," Fierce Biotech. July 30, 2014. Available from:http://www.fiercebiotech.com/press-releases/biomarin-sells-priority-review-voucher-675-million/. (Accessed 27 August 2014)

[4]Food and Drug Administration (U.S.). Orphan Drug Act. 2013 July 18. Available from: http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/orphandrugact/default.htm. (Accessed 27 August 2014)

pricing tier is also made available in the regions where the license to bedaquiline has already been granted to other distributors, for example in Russia and the former Soviet Union (FSU) states where there are large DR-TB burdens.

We also strongly urge Janssen to re-consider the current lowest available price of the drug for all non-high income markets. Lower prices for government purchasers, non-governmental organizations and other treatment providers can be achieved by Janssen lowering the price after consultations with TB stakeholders, and offering voluntary licenses.

We request clarity as to whether Janssen will license any generic companies to manufacture and market bedaquiline. We strongly encourage Janssen to grant non-exclusive voluntary licenses, with a reasonable royalty rate, that enable licensees to market bedaquiline to all non-high income markets, and to have the ability to develop any appropriate combination or formulation.

We note that failure to institute significant price reductions or to successfully negotiate voluntary licenses could lead countries to consider using compulsory licensing in the future to ensure access to bedaquiline, should the drug's positive impact be more definitively demonstrated. More importantly, failure to introduce or stimulate further price reductions for bedaquiline may well lead to avoidable suffering and death.

We thank Janssen for its efforts to develop this important drug and make it available through compassionate use. As Janssen transitions from compassionate use to marketing a registered drug in more countries, we ask you to ensure that the drug is priced affordably and/or that non-exclusive voluntary licenses with a broad geographic scope are granted in order to generate price reductions through generic competition.

As such, we invite you to meet on September 24, 2014 during the Critical Path to TB Drug Regimens workshop with the signatories of this letter, as well as key funders of TB drug procurement and policymakers (USAID, UNITAID, the World Health Organization, the Global Fund to Fight AIDS, TB and Malaria, and TB programs), to determine solutions to improve affordability. We also request a deadline of October 28, 2014 for Janssen to set out a revised pricing structure. We urge your response to this letter by September 17, 2014.

Thank you,

AIDS-Free World
Prof. Graham Bothamley, Chair, TBNET*
Community Research Advisors Group (CRAG)
Dr. Jennifer Furin, TB Research Unit, Case Western Reserve University*

(endorsements continued on next page)

European Community Advisory Board (ECAB) of the European AIDS Treatment Group (EATG)
Global Coalition of TB Activists (GCTA)
Global Health Advocates
Global TB Community Advisory Board (TB CAB)
Dr. Cristoph Lange, Head, Clinical Infectious Diseases, Medical Clinic Research Center Borstel*
Médecins Sans Frontières Access Campaign
Partners In Health
RESIST-TB
RESULTS
RESULTS International Australia
RESULTS UK
Dr. Michael Rich, Partners In Health
Stop TB Partnership
TB Proof
TB Europe Coalition
Treatment Action Group (TAG)

***Note: For individual signatories, institutions listed as affiliations only**

Additional CCs: (in alphabetical order)

Dr. Draurio Barreira, Coordinator, National TB Control Program, Brazil
Ambassador Deborah L. Birx, U.S. Global AIDS Coordinator
Mr. Donal Brown, Head, Global Funds Department, U.K DfID
Dr. Erlina Burhan, Head Pulmonologist, Persabahatan Hospital in Indonesia
Mr. José Luis Castro, Executive Director, International Union Against TB and Lung Disease
Mr. Philippe Douste-Blazy, Chair, UNITAID
Dr. Philippe Duneton, Executive Director ai, UNITAID
Dr. Mark Dybul, Executive Director, Global Fund to Fight AIDS, TB and Malaria
Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. R. S. Gupta, Deputy Director General, Indian RNTCP
Dr. Gilla Kaplan, Director, Tuberculosis, Bill and Melinda Gates Foundation
Dr. Joel Keravec, Manager, Global Drug Facility
Dr. Susan Maloney, Global TB Coordinator, U.S. CDC
Dr. Aaron Motsoaledi, Minister of Health, South Africa
Ambassador Philippe Meunier, Ministry of Foreign and European Affairs of France
Dr. Ariel Pablos-Mendez, Assistant Administrator for Global Health, USAID
Dr. Phuong Nguyen Thi Mai, National Treatment Program, Vietnam
Dr. Yogan Pillay, Deputy Director General, National Health Department, South Africa
Dr. Shri Anshu Prakash, Joint Secretary, Indian Ministry of Health & Family Welfare,
Dr. Mario Raviglione, Director, Global TB Program, World Health Organization
Dr. David Ripin, Executive Vice President of Access Programs and Chief Science Officer, Clinton Health Access Initiative
Dr. K. S. Sachdeva, Chief Medical Officer, Indian RNTCP
Dr. Rajiv Shah, Administrator, USAID
Mr. Michel Sidibe, Executive Director, UNAIDS
Ms. Cheri Vincent, Chief, Infectious Diseases Division, USAID
Mr. David Wilson, Global AIDS Program Director, World Bank
Dr. Wang Yu, Director, Chinese CDC