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The Global TB CAB
c/o Erica Lessem, MPH
Treatment Action Group (TAG)
261 Fifth Avenue, Suite 2110
New York, NY 10016 USA

7 August 2015

Subject: Bedaquiline Compassionate Use Program

Dear Members of the Global TB CAB,

We would like to inform you that Janssen has made a decision to end the global bedaquiline compassionate use program as of September 1, 2015.

Janssen has supported a bedaquiline compassionate use program since December 2011 for patients with pulmonary XDR- or Pre-XDR TB in countries that have legal and/or regulatory frameworks for compassionate use. To date, more than 700 people in more than 45 countries have received bedaquiline through the compassionate use program.

The approval of SIRTURO® (bedaquiline) in at least 40 countries, including MDR-TB high burden countries such as Russia, South Africa, India, South Korea, Peru, The Philippines, and the availability of SIRTURO® through the Global Drug Facility (GDF) have, in our opinion, obviated the need to continue the compassionate use program. Regulatory approval and local registration are some of the ways we can ensure sustainable access to bedaquiline. We continue to pursue registration in several countries that have significant burden of MDR-TB. We also recognize the importance of the access framework provided by the GDF in addressing certain access gaps. Our bedaquiline donation program through USAID will further allow access for patients in more than one hundred low- and middle-income countries for the next four years as these countries build their MDR-TB treatment programs.

We are grateful to all of our partners that made the compassionate use program possible as we worked to secure the regulatory approvals needed to make the treatment available through primary channels.

We welcome any feedback you may have regarding this subject, and look forward to continuing to work together to find sustainable solutions to address MDR-TB.

Sincerely,

Chrispin Kambili, M.D.
Global Medical Affairs Leader, Janssen Global Public Health
Janssen Pharmaceutical Companies of Johnson & Johnson