TO: Marco Cavaleri
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And
John Dalli
Commissioner for Health and Consumer Policy
European Commission
By email: cab-dalli-webpage@ec.europa.eu

24 May 2012

Open Letter Re: Conducting drug-drug interaction studies for bedaquiline (TMC207) and delamanid (OPC6783)

Dear Dr. Cavaleri,

We wish to draw to your attention our deep concern at development of two new products extremely important for tackling the growing epidemic of drug resistant tuberculosis (TB). Those are bedaquiline (TMC207) by Janssen and delamanid (OPC6783) by Otsuka.

These two new investigational TB drugs—the farthest along in development—are being studied in people with multi-drug resistant TB, extensively drug resistant TB (XDR-TB) and pre-XDR-TB. Both are entering phase III studies and have or are likely to be submitted to regulatory authorities this year. Yet bedaquiline and delamanid have not been studied together in the pharmacokinetic (PK) studies that will tell us how they interact and whether they are safe to use together.

However, when they are approved, it is inevitable that they will be used together in the field, because people with XDR-TB desperately need effective new oral drugs to shorten their time to culture conversion, and hopefully, cure.

Therefore, we call upon the FDA to require that the respective drug sponsors, Janssen and Otsuka, conduct the necessary PK studies to demonstrate whether the drugs are safe to use together. This requirement should be a condition for accelerated approval.

We are similarly making this request to the U.S. Food and Drug Administration. We are also in discussions with the drug sponsors to encourage the expeditious commencement of the necessary PK studies to ensure that sufficient data are available to inform guidance for the appropriate use of the two drugs in combination, once they are both approved.

We are readily available to dialogue further and look forward to your response. Please respond to Erica Lessem at erica.lessem@treatmentactiongroup.org at your earliest convenience.

Yours truly,

Polly Clayden, United Kingdom
Collen Daniels, Australia
Nathan Geffen, South Africa
Denis Godlevskiy, Russian Federation
Mark Harrington, United States
Giselle Israel, Brazil
Bactrin Killingo, Kenya
Blessina Kumar, India
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Ezio Tavora dos Santos Filho, Brazil
Wim Vandevelde, Belgium

for the Global Tuberculosis Community Advisory Board (TB CAB)