EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ms Erica Lessem
Global Tuberculosis Community Advisory Board (TB CAB)
By email: erica.lessem@treatmentactiongroup.org

22 March 2013
EMA/178361/2013
Human Medicines Development and Evaluation

Subject: Open letter regarding urgent need for new drugs to fight tuberculosis

Dear Members of the Global Tuberculosis Community Advisory Board,

Thank you for your open letter advocating for the approval of delamanid and bedaquiline, two new drugs for treatment of MDR-TB currently under assessment at the CHMP.

The Agency is fully aware of the medical need in the area of MDR and XDR TB and therefore warmly welcomes the development of new anti-tuberculosis drugs.

However, as you mention in your letter, a conclusion on the benefit risk balance of these products will have to take duly into account the currently available evidence.

In case of a positive recommendation for marketing authorisation, you can be reassured that adequate post-marketing measures will be put in place.

The EMA will also communicate in due time the outcome and details of the assessment performed by the EMA scientific committee as well as the recommended conditions for use of the medicines.

We look forward to discussing further with you this key public health topic.

Yours sincerely,

Marco Cavaleri
Head of Antiinfectives and Vaccines

Cc:
Tonio Borg, Commisioner for Health and Consumer Policy European Commission
Hans-Georg Eichler, Senior Medical Officer, EMA
Tomas Salmonson, CHMP Chairman

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu