TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

TO: Marco Cavaleri
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and

Tonio Borg
Commissioner for Health and Consumer Policy European Commission
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March 18, 2013

Open letter re: urgent need for new drugs to fight tuberculosis

Dear Dr. Cavaleri,

Since the Global TB Community Advisory Board (TB CAB) first wrote you regarding new drugs in development to fight tuberculosis (TB) on May 24, 2012, two new drugs to fight multidrug-resistant TB (MDR-TB) have been filed with the European Medicines Agency (EMA) for marketing approval. These two drugs, delamanid and bedaquiline, have the potential to fill a serious unmet medical need.

As you are well aware, TB continues to kill 1.4 million people per year according to the World Health Organization. Rates of drug-resistant TB, which are even more costly and difficult to treat, are on the rise. Existing treatment regimens for drug-resistant TB—particularly extensively drug-resistant TB (XDR-TB) and pre-XDR-TB—are lengthy, difficult to tolerate, and lack efficacy data from clinical trials.

In contrast, both bedaquiline and delamanid have promising data from phase I and II clinical trials to support their efficacy for treating MDR-TB. Questions regarding the drugs' optimal use—especially in key populations such as children and individuals co-infected with HIV—and bedaquiline's impact on mortality certainly require further investigation. Yet confirmatory data from phase III trials for both compounds are pending, and will not be available for several years.

Given the urgent need for new drugs to fight drug-resistant TB, and the commitments in place to ensure that both drugs are studied further even if granted approval, we respectfully request that you and the Committee for Medicinal Products for Human Use (CHMP) seriously consider the import of having new treatment options. Moreover, EMA

approval has the potential to signal to the people with drug-resistant TB, to drug developers, and to regulators around the world that fighting TB is and must be a priority.

We therefore urge the EMA both to be a pioneer in the TB regulatory field by approving new drugs if they are deemed safe and effective by the CHMP, and to be diligent in enforcing the required postmarketing studies that are conditions of approval.

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

Yours truly,

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