TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

To: **Lic. Juan Pablo Aparco Balboa**, Chair
Comité Institucional de Ética en Investigación
Instituto Nacional de Salud (INS)
Lima, Peru

Cc: **Dr. Leonid Lecca,** Local Principal Investigator
Dr. Patricia Garcia, Minister of Health of Peru

10 March 2017

OPEN LETTER RE: The importance of the observational "endTB" study for expanding access to new treatments for multidrug-resistant tuberculosis in Peru

Dear Members of the Committee,

As the Global TB Community Advisory Board (TB CAB), a global group of tuberculosis (TB) activists working to expedite high-quality research and access to TB drugs and diagnostics, we are writing to share our disappointment and concern regarding the committee's recent decision to reject the observational study proposed by Partners in Health (PIH)– Expanding New Drugs for Tuberculosis (endTB)– and to urge your reconsideration.

In October 2016 and February 2017, we sent letters asking the Ministry of Health (MINSA) to: (1) support the registration of delamanid in Peru; (2) ensure the inclusion of delamanid in the country's forthcoming guidelines on the management of drug-resistant TB (DR-TB); and (3) establish a mechanism for access to delamanid while registration is pending.[1,2] We also continue to hold drug sponsor, Otsuka accountable for filing for registration with the Directorate General of Medicines, Supplies and Drugs (DIGEMID), as full registration is necessary for promoting equitable and sustainable access.

However, the immediate lack of registration and in-country guidance for delamanid should not preclude its administration under the conditions of operational research being proposed by the endTB study. In fact, we believe that the lack of registration and in-country guidance are reasons to support the endTB study given its potential to inform the safe and optimal implementation of new TB treatments, delamanid and bedaquiline, under program conditions in Peru.

We also remind INS and other policymakers in Peru that the consequences of not providing important TB drugs are grave not only for patients, but for the government as well. A recent legal victory in the Delhi High Court for a TB patient who sued the public hospital that denied her new TB drug bedaquiline garnered tremendous media attention, and cost the Indian TB program, the Indian Ministry of Health and Family Welfare, and the broader government dearly both in terms of public reputation and in legal fees.[3] We would like to avoid a similarly expensive and potentially embarrassing lawsuit in Peru, and therefore urge you to explore all avenues for ensuring access to delamanid in Peru, including through this endTB observational study.

We would be happy to further discuss the importance of the observational endTB study and our reasons for encouraging its approval. Before 20 March 2017, we require a response, which can be directed to the chair of the TB CAB, Wim Vandevelde at wim@eatg.org.

Respectfully submitted,

Lindsay McKenna
On behalf of the TB CAB

[1] The Global TB Community Advisory Board. Advocates call for the Ministry of Health in Peru to facilitate access to delamanid [Internet]. 17 October 2016. Available from: http://www.tbonline.info/posts/2016/10/19/advocates-call-ministry-health-peru-facilitate-acc/.

[2] The Global TB Community Advisory Board. Advocates maintain pressure on the Ministry of Health to facilitate access to delamanid in Peru [Internet]. 10 February 2017. Available from: http://www.tbonline.info/media/uploads/documents/peru_dlm_access_letter_final.pdf.

[3] Kirby T. Landmark legal ruling sees Indian girl prescribed bedaquiline for XDR-TB. Lancet Respir Med 2017. 3 February 2017. Available from: http://www.thelancet.com/pdfs/journals/lanres/PIIS2213-2600(17)30042-5.pdf.