The 20th Expert Committee on the Selection and Use of Essential Medicines
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland

30 January 2015

Re: Support for adding delamanid to the Model List of Essential Medicines

We write in support of the addition of delamanid to the Model List of Essential Medicines. One of only two new drugs approved to treat multidrug-resistant tuberculosis (MDR-TB), delamanid has potential to dramatically improve the current poor treatment success rates for MDR-TB.

Delamanid has received approval for MDR-TB from several regulatory authorities. The WHO has released interim guidelines on delamanid, supporting its use for a range of patients with MDR-TB.[1] Delamanid's phase III trial has long completed enrolment and is expected to produce results shortly; delamanid's sponsor Otsuka has also initiated pediatric studies for the drug.[2,3] In the meantime, several phase I and II clinical trials have provided data indicating delamanid's safety and improvement of culture conversion rates and time to culture conversion (important surrogate markers of efficacy for TB drugs), and its lack of interactions with medicines for treating HIV.[4,5]

Yet delamanid remains unavailable to the vast majority of patients who would benefit from it, and to TB care providers and programs who are struggling to meet

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[1] World Health Organization. (2014). Interim guidance on the use of delamanid to treat MDR-TB. Geneva: World Health Organization. Available from: http://apps.who.int/iris/bitstream/10665/137334/1/WHO_HTM_TB_2014.23_eng.pdf?ua=1. (Accessed 2015 January 25).

[2] ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (U.S.) 2000. Identifier NCT01859923, A 6-month safety, efficacy, and pharmacokinetic trial of delamanid in pediatric patients with multidrug resistant tuberculosis; 2011 August 25 (cited 2015 January 25). Available from: https://clinicaltrials.gov/ct2/show/NCT01424670?term=delamanid&phase=2&rank=1.

[3] ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (U.S.) 2000. Identifier NCT01424670, Safety and Efficacy Trial of Delamanid for 6 Months in Patients With Multidrug Resistant Tuberculosis; 2013 May 15 (cited 2015 January 25). Available from: http://clinicaltrials.gov/ct2/show/NCT01859923?term=delamanid&rank=1.

[4] Gler MT, Skripconoka V, Sanchez-Garavito E, et al. Delamanid for multidrug-resistant pulmonary tuberculosis. N Engl J Med. 2012 Jun 7;366(23):2151–60. doi: 10.1056/NEJMoa1112433.

[5] Otsuka Novel Products GmbH. Labelling and package leaflet: Deltyba. 2014 April. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002552/WC500166232.pdf. (Accessed 2015 January 25).

their needs. In addition to efforts required from the company's side to register the drug more widely (particularly in the countries where it conducted clinical trials), make it more accessible under pre-approval access mechanisms, and ensure affordability, inclusion in the List would be useful in facilitating drug access and generating country-level demand for this important treatment option.

If you have questions or would like to discuss further, we welcome you to please contact erica.lessem@treatmentactiongroup.org.

Best,
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