

Request to Update WHO Recommendations on Delamanid to Include Children

March 24, 2016

TO: Christian Lienhardt, Karin Weyer, Diana Weil, Mario Raviglione, Malgorzata Grzemska

CC: Janet Ginnard, Cherise Scott, Brenda Waning, Elihud Wandwalo, Mohammed Yassim, Cheri Vincent, YaDiul Mukadi

Dear Christian, Karin, Diana, Mario and Malgosia,

We write to share with you our excitement about two recent developments with the new drug delamanid that stand to have a great impact on the treatment of children with TB. First was the announcement from the Global Drug Facility that it will soon have delamanid available for procurement. The second is the emerging data on the dosing, pharmacokinetic, and short-term safety data for delamanid in children as young as 6 years of age and with weights as low as 20kg. In fact, Otsuka has now incorporated these new data into their global compassionate use protocol. For the first time, we are poised to begin offering children the same standard of care that is offered to adults with resistance or intolerance to second-line drugs: therapy with a novel agent.

We are asking the WHO to partner with us as we move forward to improve access for children to the first new TB drug with a pediatric indication in almost half a century. We were impressed with the speed with which the WHO was able to issue guidance on the programmatic use of delamanid. However, we note with concern that this guidance states that the recommendations are for adults >18 years of age. We realize that, at the time that this guidance was drafted, there were no data on delamanid in children. Such data now exist and we urge the WHO to rapidly issue and update the 2014 delamanid guidance. Furthermore, since there will soon be data on children under the age of 5, we request that you consider how to rapidly update the WHO guidance documents when those data become available so that these can be updated promptly.

Currently, children with resistance or intolerance to second-line drugs are receiving substandard therapy: these children need to have immediate access to delamanid. The cost of procuring the drug may be prohibitively expensive for some countries, and many programs will not be able to begin procuring the drug until the WHO guidelines are updated. We know that you stand with us in doing everything possible to improve the treatment of children with MDR-TB and are confident you will find a way to issue this updated guidance.

We would like to have a follow up call to discuss these issues with you in the next 10 days. Please let us know your availability and thank you for all you do on behalf of children with TB.

Sincerely,

The Sentinel Project on Pediatric Drug-Resistant Tuberculosis



and Treatment Action Group

TAG

Treatment Action Group

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