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Geneva, March 5, 2014

TO: Treatment Action Group (TAG)
The Global Tuberculosis Community Advisory Board (TB CAB)
TB Community Research Advisors Group (CRAG)

CC: Mark Harrington
Colleen Daniels
Erica Lessem

Dear Members of the TAG, TB CAB and CRAG,

Following recent telephone and email interactions between our organizations in response to your requests for information, we felt it was important to more formally address some of the details concerning our compassionate use and access initiatives in order to avoid inaccuracies or misrepresentations.

Otsuka shares the frustration of the TB community with the lack of new treatment options available for MDR-TB. For too long, patients have suffered with medications that have grown increasingly ineffective to drug-resistant strains. It is for this reason that we are encouraged by the recent favourable opinion of Otsuka's novel compound for MDR-TB, Deltyba™ (delamanid), from the Committee for Medicinal Products for Human Use of the European Medicines Agency. We hope to receive final European Commission approval shortly and plan to make Deltyba available to appropriate European patients who may benefit from the medicine as quickly as possible.

At the same time, we recognize that local regulations in individual European countries make it difficult to provide immediate access on day one and that an approval in Europe does not provide patients with access in other high-burden countries where we have filed or plan to file separate regulatory submissions.

Therefore, in the interest of helping patients most in need while the regulatory process continues, Otsuka has established a framework for reviewing requests and has already started making Deltyba available for compassionate use where local regulations allow. As you know, this framework includes, but is not limited to, our agreement with Médecins Sans Frontières (MSF) to supply Deltyba for compassionate use within their network of treatment sites.

In fact, Deltyba was recently made available to a patient in Europe after receiving a request from the treating physician, approval from local regulatory bodies and an evaluation by an Otsuka internal review committee. Once final approval was secured from the ethics board of the hospital, Otsuka moved quickly to get Deltyba into the hands of the treating physician and we remain in close contact to monitor the situation and provide any necessary support on administrating Deltyba.

The decision to provide access to Deltyba for compassionate use was not taken quickly or lightly. The TB community has waited nearly half a century for new medications to be introduced and we could not squander this opportunity by rushing into a programme without fully evaluating all parameters. To help the greatest number of patients worldwide, it is important that the community work together on rational approaches to compassionate use that ensure novel compounds are delivered in a responsible manner to minimise the development of drug resistance.

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We would like to take this opportunity to invite the leadership of your organizations to a meeting in our Geneva office where Otsuka may walk you through the details of our compassionate use framework and answer any questions you may have.

Future Access Plans

In the past we have also discussed a number of topics regarding Deltyba, from the need for affordable pricing upon approval, to ongoing registration in high-burden countries, and further research to optimize its use. Let me assure you that Otsuka is committed to performing all of the above.

In fact, our team is currently exploring partnerships with leading multinational research institutions with experience in MDR-TB control to conduct a series of optimization studies to determine if the addition of Deltyba to existing regimens may successfully simplify current treatments. These will take place in high-burden settings.

Finally, applications are being prepared in all high-burden countries where we have conducted clinical trials. However, in order for these to proceed we must first obtain approval in Europe.

Like you, we firmly believe that everyone has a role to play when it comes to providing new treatment options for TB. One of the fastest and broadest ways to provide access to the highest number of patients starts with appropriate regulatory approvals. As a manufacturer, we plan to do our part to continue investing in TB R&D and rolling out Deltyba in a safe and responsible manner. We hope that the advocacy community will join us in working towards viable, safe and sustainable solutions.

As you noted in your latest TB R&D Funding report, more and more companies are continuing to back away from investing in neglected diseases like TB. Otsuka is proud to remain the largest private investor of TB R&D worldwide but new medicines are only part of the equation. Without addressing other important aspects such as hospitalization and diagnostic costs, scaling up infrastructure and TB prevention, our efforts will not be enough. Let's move forward together on cost-effective solutions that work.

I look forward to continuing the dialogue and will follow-up with you concerning the proposed meeting in Geneva.

Best regards,

Dr. Patrizia Carlevaro
Managing Director

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