# *Otsuka Announces Worldwide Access Plan for Delamanid with Stop TB Partnership's Global Drug Facility*

- ***Innovative public-private partnership opens access to delamanid, a recently approved medication in the European Union, Japan and the Republic of Korea, for the treatment of multidrug-resistant tuberculosis (MDR-TB), to more than 100 low- and middle-income countries that may procure anti-TB medications through GDF***
- ***Agreement includes package of services and technical assistance to help countries incorporate delamanid into their existing treatment programmes***
- ***MDR-TB remains a major global health concern with 480,000 people infected each year and only a 50% treatment success rate[1]***

**Munich, Germany (February 24, 2016**) - Recognizing the immediate need for access to new therapeutic options for multidrug-resistant TB (MDR-TB), Otsuka Novel Products GmbH (Otsuka) today announced an ambitious new public-private partnership with the Stop TB Partnership (Stop TB) to increase access and scale-up treatment of delamanid (Deltyba™) in low- and middle-income countries.

Any country that is eligible for TB financing from the Global Fund to Fight AIDS, TB and Malaria and follows World Health Organization (WHO) guidelines for the proper management of MDR-TB in quality-assured programs may apply to Stop TB's Global Drug Facility (GDF) to incorporate delamanid into their national treatment programmes. It is estimated that more than 100 countries may now be eligible to access delamanid through the GDF.

"This agreement with the Stop TB Partnership is only the first step in assuring wider, equitable access to delamanid," said Masuhiro Yoshitake, managing director of Otsuka and TB Global Project leader. "Otsuka is committed to working with all stakeholders in the TB community to scale-up delamanid use in a rational way that supports larger efforts to combat antimicrobial resistance."

"Our goal is to ensure all people with TB have access to the best possible treatment. Until now, delamanid was not available for procurement in low- and middle-income countries. We are hopeful that this partnership is going to help give countries more tools and more options to fight MDR-TB in their communities," said Dr Lucica Ditiu, executive director of the Stop TB Partnership.

By establishing a formalized partnership that goes beyond the supply of medicine, Otsuka and Stop TB will work more closely to support communities with education, training, technical assistance, and TB advocacy activities.

This partnership is only one component of Otsuka's "FighTBack Initiative" which incorporates innovative research and development, collaborative capacity building, responsible access to patients and optimised patient management. Beyond delamanid, the initiative includes the

development of a first-ever paediatric formulation for MDR-TB, diagnostic solutions, mHealth tools, and potential future anti-TB drug candidates. Otsuka is also engaging in close to a dozen third-party research collaborations looking at shorter, more effective and more patient-friendly ways to fight MDR-TB. Included in this, Otsuka is proud to work with Médecins Sans Frontières, Partners in Health and Interactive Research & Development on the endTB project which will evaluate new regimens for the treatment of MDR-TB and reduce existing country-level barriers to the uptake of new TB drugs while building a broader evidence-base for WHO recommendations.

**About Delamanid**

The efficacy of delamanid was studied in a large, randomized, placebo-controlled phase 2 trial that included a 2-month treatment period and a 1-month follow-up of 481 MDR-TB patients (Trial 204), with 213 patients continuing to a 6-month open-label treatment trial (Trial 208), and concluding with a 24-month follow-up study of 421 out of the originally randomized 481 patients (Trial 116). Adding 100 mg delamanid twice daily to a WHO-recommended optimized background regimen (OBR) was associated with a statistically significant 53% increase (p=0.008) in the percentage of patients achieving sputum culture conversion (SCC) at 2 months (45.4%) compared to those with placebo added (29.6%).[2,3]

SCC is an indicator of when a patient is no longer infectious. The more rapid clearance of TB bacilli is important since SCC at two months is strongly correlated with improved patient outcomes.

Clinical trial results demonstrated that adverse events were evenly distributed in the delamanid and placebo treatment groups with the exception of QT prolongation. Electrocardiogram QT prolongation was reported in 9.9% of patients receiving delamanid as 100 mg twice daily compared to 3.8% of patients receiving placebo plus OBR. This was not accompanied by any clinical symptoms such as syncope or arrhythmias.[2]

A Phase 3 trial of delamanid is fully enrolled, and involves six months of treatment with delamanid plus OBR in patients with MDR-TB, including those with co-existing HIV infection. The trial is taking place in Estonia, Latvia, Lithuania, Moldova, Peru, the Philippines, and South Africa with results expected in 2018. Additionally, enrollment continues for a clinical program exploring the use of delamanid in pediatric MDR-TB and is evaluating a dispersible formulation for use with younger children and infants.

Delamanid has received regulatory approval in the European Union, Japan and the Republic of Korea and registrations are underway in China, Hong Kong, Indonesia, Philippines and Turkey; delamanid is not currently approved in the US. In 2014, the WHO published an interim policy guidance on “The Use of Delamanid in the Treatment of Multidrug-Resistant Tuberculosis”[4] and in 2015 delamanid was added to the WHO’s Essential Medicines List.

For more information, please visit: http://otsuka-onpg.com/

**MEDIA CONTACT:** Marc Destito
Communications Director, Global TB Project mdestito@otsuka.ch ; +41-78-881-03-22

###

1 World Health Organization. Global Tuberculosis Report 2015. Geneva, Switzerland. WHO/HTM/TB/2015.22

2 Gler MT, Skripconoka V, Sanchez-Garavito E, et al. Delamanid for multidrug-resistant pulmonary tuberculosis. N Engl J Med. 2012;366:2151-60

3 SCC for groups dosed with delamanid were statistically higher compared to placebo (45.4-29.6/29.6=0.5333) (p=0.008). Results from secondary analysis of SCC based on solid media were consistent with those of the primary analysis. The study found that by the end of week five, 24% of subjects in the delamanid 100 mg BID group achieved SCC compared with 13% of study subjects in the placebo group.

4 World Health Organization. The use of delamanid in the treatment of multidrug-resistant tuberculosis - interim policy guidance. 2014, Geneva, Switzerland. WHO/HTM/TB2014.23