**Otsuka and Mylan Announce License Agreement to Commercialize Delamanid (Deltyba™) for Multidrug-Resistant Tuberculosis (MDR-TB) in High-Burden Countries**

Otsuka Pharmaceutical Co. Ltd. (Otsuka) and Mylan N.V. (NASDAQ, TASE: MYL) have entered into a license agreement between their respective subsidiaries, Otsuka Novel Products GmbH (ONPG) and Mylan Pharmaceuticals Private Limited (Mylan), to commercialize delamanid for the treatment of adults with pulmonary multidrug-resistant tuberculosis (MDR-TB) in low- and middle-income countries. Delamanid was discovered and developed, and is currently marketed by Otsuka under the brand name Deltyba™.

Under the terms of the agreement, Mylan has been granted an exclusive license by Otsuka to prioritize access to Deltyba™ in South Africa and India. Both countries are considered by the World Health Organization (WHO) as among the highest-burden countries for MDR-TB and TB/HIV co-infection, with over 150,000 estimated new cases of MDR-TB/rifampicin-resistant TB in 2015 alone.[1] The Drug Controller General of India (DCGI) granted approval to Mylan to market Deltyba™ in India, and registration is under way in South Africa.

Mylan is anticipated to further exercise exclusive commercial rights and registration responsibilities in additional countries, including many other high MDR-TB burden countries where Otsuka does not have a commercial presence. The agreement announced today also allows both companies to enter into discussions and feasibility studies for a technology transfer plan, enabling Mylan to manufacture and distribute Deltyba™ for these markets in the future.

“Otsuka is a global leader in TB research and development and Mylan is a recognized leader in the provision of high-quality medicines for infectious diseases in many developing countries,” said Tatsuo Higuchi, president and representative director. “Given our respective experience in the field, our two companies are well positioned to work together in the fight against MDR-TB.”

Mylan President Rajiv Malik commented, “Mylan’s mission is to provide access to medicine to the world’s 7 billion people, including those in the developing world where the need for medicines like Deltyba™ are great and the challenges to reaching patients with high quality medicines are high. We are proud to partner with Otsuka to help deliver this important medicine in the highest-burden countries and provide more MDR-TB patients with access to treatment.”

Deltyba™ is one of two anti-tuberculosis medicines recently approved, after more than 40 years of treatment with the same agents. It is registered in the European Union, Japan, the Republic of Korea, Hong Kong, Turkey and India. Since regulatory approval, more than 4,000 treatment courses of Deltyba™ have been shipped for use in over 50 countries. Otsuka recently launched a novel, pre-approval access program in South Africa administered by the Department of Health and a similar rollout programme in India is ready to begin.

**About Deltyba™**

The efficacy of Deltyba™ was studied in a large, randomised, 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 Deltyba™ twice daily to a WHO-recommended OBR was associated with a statistically significant 53% increase (p=0.008) in the percentage of patients achieving SCC at 2 months (64/141, 45.4%) compared to those with placebo added (37/125, 29.6%).[2] The reported mortality rate was lower in patients receiving Deltyba™ for at least 6 months (2/192 (1.0%) compared with those receiving Deltyba™ for 2 months or no Deltyba™ (19/229 (8.3%); p<0.001).[3]

Clinical trial results demonstrated that Deltyba™ is well tolerated with adverse events evenly distributed in the Deltyba™ and placebo treatment groups with the exception of QT prolongation. Electrocardiogram QT prolongation was reported in 9.9% (16/161) of patients receiving Deltyba™ as 100 mg twice daily compared to 3.8% (6/160) of patients receiving placebo plus OBR. This was not accompanied by any clinical symptoms such as syncope or arrhythmias.[2]
Publication of results of the phase 3 study to confirm the safety and efficacy of Deltyba™ is expected in 2018, and a paediatric investigational programme is underway.

**About TB & MDR-TB**

Tuberculosis (TB), an airborne infectious disease, is among the top causes of death in the world and is the leading infectious disease killer. Drug resistance poses a real challenge to fighting and treating TB. Globally in 2015, nearly half a million people developed MDR-TB, an infection resistant to at least isoniazid and rifampicin, the two most commonly used first-line TB drugs.[1] Mycobacterial MDR strains with additional resistance to at least one fluoroquinolone drug and a second-line injectable agent are defined as extensively drug-resistant (XDR). Secondary or acquired resistance has its roots in inappropriate treatment.

Resistance to anti-tuberculosis drugs worsens the prognosis for a successful treatment outcome. The treatment of MDR-TB combines at least five drugs – active or presumed active against the resistant strain – for an extended period of up to 20 months or more depending on patient response. The anti-TB drug combinations are chosen depending on the patterns of resistance from drug susceptibility testing and tolerance.

TB is the leading killer of HIV-positive people: about 35% of HIV deaths were due to TB in 2015. That year, there were an estimated 1.2 million new cases of TB amongst people who were HIV-positive, 71% of whom were living in Africa.[1]

**About Mylan**

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com.

*This press release includes statements that constitute "forward-looking statements," including with regard to Mylan further exercising exclusive commercial rights and registration responsibilities in additional countries, Mylan manufacturing and distributing Deltyba™ for other markets in the future and that a pre-approval access program in India is ready to begin. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any*

*such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.*

**About Otsuka**

Otsuka Pharmaceutical Company, Ltd., a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan, is a global healthcare company with the corporate philosophy: "Otsuka - people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

Otsuka Novel Products GmbH (ONPG), a subsidiary of Otsuka Pharmaceutical Company, Ltd., is dedicated to finding innovative solutions to fight the global pandemic of tuberculosis (TB). As the European marketing authorization holder for Deltyba™, Otsuka Novel Products GmbH works in collaboration with other Otsuka Group companies, partners, non-governmental organisations and other stakeholders, to expand global access to Deltyba™ and fight multidrug-resistant TB.

**References:**

[1]World Health Organization. Global tuberculosis report 2016. WHO/HTM/TB/2016.13.

[2]Gler MT, et al. Delamanid for multidrug-resistant pulmonary tuberculosis. *New England Journal of Medicine* 2012; **366**: 2151–2160.

[3]Skripconoka V, et al. Delamanid improves outcomes and reduces mortality in multidrug-resistant tuberculosis. *European Respiratory Journal* 2013; **41**: 1393–1400.