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Positive results for Otsuka's MDR-TB treatment

07 June 2012 | News | By BioSpectrum Bureau

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Singapore: Clinical trial results on the safety and efficacy of delamanid, Otsuka Pharmaceutical's investigational compound for the treatment of multidrug-resistant tuberculosis (MDR-TB), showed a 53 percent increase in sputum culture conversion (SCC) after two months between study subjects receiving delamanid 100 mg twice-daily (BID) plus a background regimen (BR) consistent with WHO treatment guidelines compared with subjects receiving placebo plus BR alone.

The result was published in the *New England Journal of Medicine*. Delamanid is from a class of compounds, known as nitro-dihydro-imidazooxazoles, which work by inhibiting synthesis of mycolic acid.

In the past two decades, MDR-TB has emerged as a significant public health threat, with strains of TB growing increasingly resistant to treatment with first-line anti-TB drugs. The WHO Global Plan to Stop TB 2011-2015 has called for urgent development of new drugs with novel mechanisms of action to treat all forms of TB, including MDR-TB, which is more difficult to cure and has higher mortality rates compared to regular TB.

"TB treatment has been a priority for Otsuka for more than 30 years, and over time we have become the largest private funder of TB research and development. We are committed to addressing the urgent need for short, simple, well tolerated regimens that are effective in patients who are resistant to current regimens," said Mr Masuhiro Yoshitake, executive operating officer of Otsuka Japan and TB Global Project Leader. "The findings published today are a major step forward for the TB community and offer compelling support for bringing delamanid to market as one of the first new drugs to treat TB in more than 40 years."

The delamanid trial was a double-blind, randomised, placebo-controlled study conducted in 17 centers in nine countries. The trial was designed to evaluate the safety, tolerability, efficacy, and pharmacokinetics of two doses of delamanid, 100 mg BID and 200 mg BID, each administered with BR, compared with placebo administered with BR. The BR was consistent with World Health Organization (WHO) recommendations for the treatment of MDR-TB. Study subjects were treated for eight weeks, during which they were hospitalised for intensive safety monitoring and sputum culture assessment.