New TB Compound to be developed for Pan-TB Regimen

31 October 2016, Geneva, Switzerland - During the 47th Union World Conference on Lung Health, Otsuka Pharmaceutical, the manufacturer of delamanid, announced the development of a second anti-TB compound in its portfolio currently in Phase 1 clinical development. The compound, OPC-167832, is intended to target both drug-susceptible as well as drug-resistant forms of TB, and has a different mechanism of action than all currently approved anti-TB drugs.

With support from the Bill & Melinda Gates Foundation, Otsuka is working on a concept of developing OPC-167832 as part of a novel Pan-TB regimen that would also contain delamanid and one or two other new anti-TB drugs, in line with World Health Organization's recently published guidance on Target Regimen Profiles for TB Treatment (http://www.who.int/tb/publications/TRP_profiles/en/). The regimen selection will be guided, in part, through data gathered from collaborations with the Critical Path to TB Drug Regimens (CPTR) and the US National Institutes of Health (NIH).

"To win the fight against TB we need not only new drugs, but entirely new regimens that would simplify and shorten treatment against all forms of TB—regardless of drug susceptibility," said Dr. Lucica Ditiu, Executive Director of the Stop TB Partnership. "The announcement of a public-private collaboration on the clinical development on a Pan-TB treatment approach is very welcomed news and the TB community looks forward to closely tracking the scientific outcomes of these early clinical studies."

Otsuka reported it is developing OPC-167832 in combination with delamanid. Mouse models of chronic TB studies showed that these two compounds, along with one or two other new anti-TB drugs, are more effective than standard regimens against both drug-susceptible as well as multidrug-resistant TB. Early results suggest that regimens with OPC-167832 and delamanid at the core could potentially shorten treatment duration and improve treatment outcomes. The US FDA has already granted the investigation of OPC-167832 a Fast Track status, and human trials are underway.

The development program for a Pan-TB regimen will be supported by another novel technology that provides a quantitative measurement of lipoarabinomannan (LAM) in sputum. The technology is intended to create the possibility of assessing a patient's treatment progress in near real-time, opening the potential for truly adaptive clinical trial designs. Otsuka is piloting this tool together with CPTR to seek qualification of this assay as an Innovative Drug Development Method/Tool.

For more information on OPC-167832, delamanid, and the development approach towards shorter, safer, simplified TB treatment, presentations delivered at the 47th Union World Conference on Lung Health may be accessed here: [http://www.professionalabstracts.com/union2016/iplanner/#/grid].