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Ono Conducts the Nation's First Microdosing Study Using Its Novel and Innovative Drug Candidate

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced today that Ono has conducted the nation's first microdosing study, in which a minute amount of a novel and innovative drug candidate is administered to human to analyze its pharmacokinetics.

A microdose trial is intended to confirm, before the start of full clinical development, absorption and distribution of a drug to a target organ through the administration of doses exhibiting no drug efficacy and toxicity to healthy volunteers. The Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Economy, Trade and Industry (NEDO project) of Japan also encourage microdosing studies as an effective approach to streamline the drug development. This time, Ono conducted the first microdosing study using its novel and innovative drug candidate in Japan, and as a result, obtained the desired result. Ono will actively incorporate into new drug development process early-stage and exploratory clinical trials including microdosing studies to improve efficiency of drug discovery research and furthermore develop new drugs more successfully. Ono believes this approach will allow creating innovative drugs of Japanese origin.

About Exploratory Clinical Trials

Exploratory clinical trials are intended to obtain human physiological or pharmacological findings of a novel and innovative drug candidate before the start of full clinical development. These trials are, based on the dose level, classified roughly into microdosing studies and studies at sub-therapeutic doses or into the anticipated therapeutic range. In a microdosing study, for example, the drug is administered to human at a dose of ≤ 100 μg exhibiting no efficacy and toxicity to investigate absorption, target receptor binding or tissue distribution. Please see "Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals M3(R2) (issued by MHLW in February 2010)" for details.