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ONO PHARMACEUTICAL CO., LTD.

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Code No.: 4528 at the 1st section of the Tokyo / Osaka Stock Exchange
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NDA Submission in Japan for Onoact® 50 for Injection, Short-Acting Selective β_1 Blocker for Improvement of Image Quality of Coronary Arteries for Coronary CT Angiography

Ono Pharmaceutical Co., Ltd. announced today that an application for an additional indication of Onoact® 50 for Injection (INN: landiolol) for improvement of image quality of coronary arteries for coronary computed tomographic (CT) angiography was filed to the Ministry of Health, Labour and Welfare of Japan.

Coronary angiography with CT has recently attracted attention as a method diagnosing severity of coronary stenosis in patients with ischemic cardiac diseases such as angina and acute myocardial infarction. Unlike coronary angiography with cardiac catheter, the test is less invasive without requiring arterial puncture. It is also simple and convenient because it can be done on an outpatient basis within a relatively short time. However in patients with increased heart rate the test often provides low quality of imaging making a correct diagnosis difficult, and therefore it is necessary to reduce their heart rate before its performance.

Onoact® 50 for Injection, selectively blocking β_1 receptors mainly located in the heart, is expected to provide clearer image in coronary angiography with CT by swiftly reducing heart rate in patients with increased heart rate.

Onoact® 50 for Injection is a short-acting selective β_1 blocker discovered and developed by Ono, and was approved for the emergency treatment for intraoperative tachyarrhythmia (atrial fibrillation and flutter and, sinus tachycardia) in Japan in July 2002. Additionally it was also approved for post-operative tachyarrhythmia (atrial fibrillation and flutter, and sinus tachycardia) with monitoring of circulatory dynamics in October 2006. The drug has been administered to a large number of patients since the first approval.