September 14, 2011

## **ONO PHARMACEUTICAL CO., LTD.**

President and Representative Director: Gyo Sagara, Code No.: 4528 at the 1<sup>st</sup> section of the Tokyo / Osaka Stock Exchange INQUIRIES: Kinya Morimoto, Executive Officer, Director, Corporate Communications

## Launch of Corebeta<sup>®</sup> for Injection 12.5mg for Improvement of Image Quality in Coronary CT Angiography in Japan

Ono Pharmaceutical Co., Ltd. announces that it launches Corebeta<sup>®</sup> for Injection 12.5mg for Injection (INN: landiolol) for improvement of image quality of coronary computed tomographic (CT) angiography on September 15, 2011 in Japan. This is the first drug to improve image quality of coronary CT angiography in the world.

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 period of time. However the test often causes increase in heart rate and provides low quality of imaging making a correct diagnosis difficult, and therefore it is necessary to reduce their heart rate only during such short period of time for the performance of the test.

Corebeta<sup>®</sup> selectively blocks beta-1 receptors mainly located in the heart, and is expected to provide clearer image in coronary angiography with CT by swiftly reducing heart rate in patients with increased heart rate.

Corebeta<sup>®</sup> contains an identical drug substance to Onoact<sup>®</sup> 50 for Injection. The drug is a short-acting selective beta-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.

The launch of Corebeta<sup>®</sup> for Injection 12.5mg has little impact on the mid-term consolidated financial results of the company.

## PRODUCT SUMMARY

Product name:	Corebeta <sup>®</sup> for Injection 12.5mg
Generic name:	Landiolol Hydrochloride
Indication:	Improvement of image quality of coronary arteries for coronary computed tomographic (CT) angiography in patients with increased heart rate
Dosage regimen	0.125mg per kg of Landiolol Hydrochloride is administered by intravenous injection in one minute.
Distinctive features:	<ol> <li>Corebeta<sup>®</sup> for Injection 12.5mg is the first drug in the world that obtained an indication of improvement of image quality of coronary arteries for coronary CT angiography in patients with increased heart rate.</li> <li>It reduces heart rate immediately after administration and the action disappears in 15 to 30 minutes. Thus it is a short-acting selective beta-1 blocker with fast-acting and easily-controlled advantage.</li> <li>It provides good image quality of coronary arteries by reducing heart rate during coronary CT angiography.</li> <li>It decreased heart rate to 65 beats per minute that is generally required to undergo angiography under low radiation in 84 out of 126 patients (66.7%).</li> <li>Incidence of adverse reactions (side effects) was observed in 5.3% (20 out of 377 patients) as of approval including abnormal laboratory test values, and those include decrease in blood pressure in 4 patients (1.1%), increase in ALT (GPT) in 3 patients (0.8%), rash in 3 patients (0.8%), increase in AST (GOT) in 2 patients (0.5%), increase in blirubin in 2 patients (0.5%) and increase in leucocyte in 2 patients (0.5%).</li> </ol>
Packaging:	Corebeta <sup>®</sup> for Injection 12.5mg: 5 vials
NHI reimbursement prices:	Corebeta <sup>®</sup> for Injection 12.5mg: JPY 2,634.00
Date of NHI price listed:	September 12, 2011
Date of launch:	September 15, 2011