

For Immediate Release

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**Daiichi Sankyo Submits Application for Additional Indication and Dosage for Ovisot®  
Intracoronary Injection 0.1g in Diagnosis of Vasospastic Angina**

**Tokyo, Japan (March 30, 2017)** – Daiichi Sankyo Company, Limited (hereafter, “Daiichi Sankyo”) today announced that it has submitted a supplemental new drug application to Japan’s Ministry of Health, Labour and Welfare (hereafter, “MHLW”) for an additional indication and dosage for Ovisot® intracoronary injection 0.1g (acetylcholine chloride) for induction of coronary spasm in spasm provocation testing during angiography.

The current indication of Ovisot® for injection 0.1g (acetylcholine chloride) is for postanesthetic paresis of intestine, acute gastric dilatation with the depressed function of the digestive tract and alopecia areata. The MHLW officially requested that Daiichi Sankyo develop Ovisot® intracoronary injection following discussions held February 3, 2016, by the Review Committee for Unapproved or Off-label Use of Drugs with High Medical Needs <sup>\*1</sup>. Following a Review Committee meeting held February 15, 2017, it was subsequently determined that an application for this additional indication based on evidence in the public domain <sup>\*2</sup> would be appropriate. A preliminary evaluation was conducted on March 2 at a meeting of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application was permitted.

Vasospastic angina is a serious condition that can lead to acute myocardial infarction and even sudden death. It is hoped that coronary spasm provocation tests performed by an intracoronary injection of acetylcholine chloride can become a valuable option for diagnosis of this condition.

As part of its Corporate Social Responsibility efforts, Daiichi Sankyo is committed to making as-yet unapproved and off-label drugs with high medical needs available to patients.

\*1 Working group held by the MHLW that aims to promote the development of drugs and indications not yet approved in Japan, but currently available in Europe and the U.S.

\*2 Application for a drug commonly known to be medically and pharmaceutically safe and with proven efficacy, for which clinical trials can be partly or entirely omitted.