

Press Release

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Daiichi Sankyo Obtains Approval in Japan for Additional Indication and Dosage for Ovisot[®] for Injection in Diagnosis of Vasospastic Angina

Tokyo, Japan (August 25, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has obtained approval in Japan for an additional indication and dosage for Ovisot[®] for injection (acetylcholine chloride) for induction of coronary spasm in spasm provocation testing during angiography.

Coronary spasm provocation tests performed by an intracoronary injection of acetylcholine chloride have been confirmed to be a valuable option for diagnosis of vasospastic angina which is a condition that can lead to acute myocardial infarction and even sudden death.

The current indication of Ovisot[®] for injection (acetylcholine chloride) is for post anesthetic paresis of intestine, acute gastric dilatation with depressed function of the digestive tract and alopecia areata. The Japanese MHLW officially requested that Daiichi Sankyo develop Ovisot[®] for injection following discussions held February 3, 2016, by the 26th Council on Unapproved or Off-label Use of Drugs with High Medical Needs^{*1}. Following the 30th Council meeting held February 15, 2017, it was subsequently determined that an application for this additional indication based on evidence in the public domain^{*2} would be appropriate.

After receiving permission from the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council at a meeting held on March 2, 2017, Daiichi Sankyo submitted a supplemental new drug application for an additional indication and dosage on March 30, 2017.

As a part of its Corporate Social Responsibility efforts, Daiichi Sankyo is committed to making 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.

Product Outline

Product name	Ovisot [®] for injection
Generic name(JAN)	Acetylcholine Chloride
Additional indication approved for manufacture and marketing	August 25, 2017
Indication (additions underlined)	 Post anesthetic paresis of intestine, acute gastric dilatation with depressed function of the digestive tract Alopecia areata <u>Induction of coronary spasm in spasm provocation testing during angiography</u>
Dosage and administration (additions underlined)	 Post anesthetic paresis of intestine, acute gastric dilatation with depressed function of the digestive tract: for adults under normal conditions, 0.1 g of acetylcholine chloride is diluted with every administration in 1 to 2 mL of water for injection, as per Japanese Pharmacopoeia, and injected subcutaneously or intramuscularly 1 to 2 times a day. Alopecia areata: for adults under normal conditions, 0.1 g of acetylcholine chloride is diluted with every administration in 5 mL of water for injection, as per Japanese Pharmacopoeia, and injected subcutaneously or intramuscularly 1 to 2 times a day. Alopecia areata: for adults under normal conditions, 0.1 g of acetylcholine chloride is diluted with every administration in 5 mL of water for injection, as per Japanese Pharmacopoeia, and injected intradermally in several locations once a week. In spasm provocation testing, acetylcholine chloride is dissolved and diluted in saline, and infused into the coronary artery 5 mL at a time. Under normal circumstances, acetylcholine chloride is infused for 20 seconds every 5 minutes in gradual doses of 20 µg, 50 µg, and 100 µg until spasms are provoked, starting with the left coronary artery. Alternatively infused into the right coronary artery for 20 seconds every 5 minutes in gradual doses of 20 µg and 50 µg until spasms are provoked.