



## Press Release

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### **Daiichi Sankyo Obtains Approval for Additional Indication and Dosage for Diagnogreen® for Injection 25 mg in Japan**

**Tokyo, Japan (July 2, 2018)** – Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) today announced that it has obtained approval in Japan for an additional indication and dosage for Diagnogreen® for injection 25 mg (indocyanine green; hereinafter, ICG) for evaluation of blood circulation in vascular and tissues (hereinafter, this indication).

The Review Committee for Unapproved or Off-label Use of Drugs with High Medical Needs<sup>\*1</sup> recommended that a public knowledge-based application<sup>\*2</sup> should be made concerning this indication, and the acceptability of a public knowledge-based application was determined by the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council on January 26, 2018. Based on this, Daiichi Sankyo submitted a supplemental new drug application for an additional indication and dosage on February 22, 2018.

This indication is already approved in Europe (including UK and Germany) and the drug is widely used in Japan as a means for mainly visual and real-time confirmation of blood circulation in various fields of surgery (vascular, cardiac, gastrointestinal, plastic, etc.)

Daiichi Sankyo is committed to making unapproved and off-label drugs with high medical needs available to patients who are waiting for them to be approved.

**\*1 Review Committee for Unapproved or Off-label Use of Drugs with High Medical Needs**

A committee established under the sponsorship of the MHLW with the aim of promoting pharmaceutical companies to develop unapproved or off-labeled drugs with indications approved in foreign countries but not in Japan.

**\*2 Public knowledge-based applications**

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	Diagnogreen® for Injection 25 mg
Generic name (JAN)	Indocyanine green
Additional indication approved for manufacture and marketing	July 2, 2018
Indications (additions underlined)	<ul style="list-style-type: none"><li>• Liver function testing (measurement of plasma disappearance rate, blood retention rate, and hepatic blood flow) Diagnosis of liver diseases, determination of healing prognosis</li><li>• Cardiovascular function testing (measurement of cardiac output, mean transit time or abnormal blood flow) Diagnosis of cardiovascular diseases</li><li>• <u>Evaluation of vascular and tissue blood flow</u></li><li>• Identification of sentinel lymph nodes in the following diseases: breast cancer, malignant melanoma</li></ul>
Dosage and administration ( Excerpt ) (additions underlined)	<p>(1) Liver function testing (Unchanged)</p> <p>(2) Cardiovascular function testing (Unchanged)</p> <p>(3) <u>Evaluation of blood circulation in vascular and tissues:</u> <u>25 mg of indocyanine green is dissolved in 5–10 mL of water for injection and is usually intravenously administered at 0.04–0.3 mg/kg depending on the purpose.</u> In the case of angiography during cerebrovascular neurosurgery, 25 mg of indocyanine green is dissolved in 5 mL of water for injection and usually intravenously administered at 0.1–0.3 mg/kg.</p> <p>(4) Identification of sentinel lymph nodes (Unchanged)</p>