Press Release

Company name: DAIICHI SANKYO COMPANY, LIMITED
Representative: Sunao Manabe, Representative Director, President and COO
(Code no.: 4568, First Section, Tokyo Stock Exchange)
Please address inquiries to Noriaki Ishida, Executive Officer,
Vice President, Corporate Communications Department
Telephone: +81-3-6225-1126
http://www.daiichisankyo.com

Daiichi Sankyo Submits Application for Additional Indication and Dosage for Diagnogreen® for Injection 25 mg in Japan

Tokyo, Japan (February 22, 2018) – Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) today announced that it has submitted a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare (hereafter, "MHLW") 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 (hereafter, this indication).

ICG is presently marketed in Japan with indications for liver function testing, cardiovascular function testing, and near-infrared fluorescence angiography during cerebrovascular surgery, and identification of sentinel lymph nodes in breast cancer and malignant melanoma. However, a petition calling for the indication, "evaluation of blood circulation in vascular and tissues", was submitted by related scientific societies, and on December 22, 2017, the 33rd Review Committee for Unapproved or Off-label Use of Drugs with High Medical Needs[*1] recommended that a public knowledge-based application[*2] should be made concerning this indication.

This application is based on the determination of the acceptability of a public knowledge-based application by the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council on January 26, 2018.

Since ICG emits fluorescence in blood when exposed to near-infrared light, it is currently used for the purposes of confirmation of blood circulation during cerebrovascular surgery, etc. The indication for which we have made the public knowledge-based application has been already approved in European countries (including UK and Germany), and the drug is expected to be used widely also in Japan as a means for visual

and real-time confirmation of blood circulation during operation 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.