

For Immediate Release

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**Daiichi Sankyo Submits Application for Additional Indication of  
Diagnogreen<sup>®</sup> Intravenous Injection**

**Tokyo, Japan (August 22, 2011)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), submitted a supplemental New Drug Application for an additional indication of Diagnogreen<sup>®</sup> (indocyanine green, hereafter, ICG) 25 mg intravenous injection for near-infrared fluorescence angiography during cerebrovascular surgery.

As a result of discussions by the Review Committee on Unapproved Drugs and Indications with High Medical Needs (hereafter, Review Committee)<sup>1)</sup> held on April 27, 2010, Daiichi Sankyo received a request to develop ICG for this indication. It was subsequently determined at a Review Committee Meeting held on June 29, 2011, that an application for an additional indication based on evidence in the public domain<sup>2)</sup> would be submitted.

A preliminary evaluation was conducted on July 29 at the meeting of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application was permitted.

This indication is based on the fluorescence property of ICG in blood by illumination with near-infrared light. ICG has been recently used for the real-time assessment of cerebral blood flow during cerebrovascular surgery, and is approved for this indication in European countries including the UK and Germany.

As a part of its CSR effort, Daiichi Sankyo is committed to making unapproved and off-label drugs available to patients who are waiting for them to be approved.

1) Working group held by the MHLW that aims to accelerate the development process for drugs not yet approved in Japan but which are 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