Daiichi Sankyo Receives Approval in Japan for Additional Indication of Diagnogreen® Intravenous Injection

Tokyo, JAPAN (February 22, 2012) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that it received approval in Japan for a supplemental New Drug Application (sNDA) for an additional indication of Diagnogreen® (indocyanine green, hereafter, ICG) 25 mg intravenous injection for near-infrared fluorescence angiography during cerebrovascular surgery.

A preliminary evaluation was conducted on July 29, 2011, at the meeting of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application1) was permitted, leading Daiichi Sankyo to submit the sNDA for an additional indication of Diagnogreen® in August.

This indication is based on the fluorescence property of ICG in blood when illuminated by 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) 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.

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