For immediate release

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Daiichi Sankyo Receives Approval for Additional Indication of Anticancer Agent Topotecin® Intravenous Drip Infusion

Tokyo, Japan (March 25, 2013) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that it received approval for a supplemental new drug application (sNDA) for an additional indication for Topotecin® intravenous drip infusion 40 mg and 100 mg (irinotecan hydrochloride hydrate) for pediatric malignant solid tumor to Japan's Ministry of Health, Labor and Welfare.

A preliminary evaluation was conducted on October 31 at the meeting of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application[1)] was permitted, leading Daiichi Sankyo to submit the sNDA for an additional indication of Topotecin® in last November.

Chemotherapy is thought to be efficacious for treating pediatric malignant solid tumor. Routine clinical practice involves treatment by a multidrug regimen according to first-line chemotherapy. The efficacy of irinotecan hydrochloride hydrate has been reported for this indication and it has been recommended as a treatment option in international textbooks and clinical practice guidelines in the last several years. The approval in Japan for the pediatric malignant solid tumor indication is the first approved additional indication for irinotecan hydrochloride hydrate in the world.

As a part of its CSR effort, Daiichi Sankyo is committed to making unapproved or off-label use of drugs with high medical needs 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.