For immediate release

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Daiichi Sankyo Submits Application for Additional Indication of Anticancer Agent Topotecin® Intravenous Drip Infusion

Tokyo, Japan (November 09, 2012) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) submitted a supplemental new drug application for an additional indication for Topotecin® 40 mg and 100 mg (irinotecan hydrochloride hydrate) for pediatric malignant solid tumor to Japan's Ministry of Health, Labor and Welfare (hereafter, MHLW).

The MHLW officially requested that Daiichi Sankyo develop Topotecin® intravenous drip infusion for this indication, as a result of discussions by the Review Committee for unapproved or off-label use of drugs with high medical needs (hereafter, Review Committee[1]) on March 23, 2012. It was subsequently determined at the Review Committee held on October 3, 2012, that an application for this additional indication based on evidence in the public domain[2] would be appropriate.

A preliminary evaluation was conducted on October 31 at the meeting of the Second Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application was permitted.

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.

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] 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