

For Immediate Release

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**Daiichi Sankyo Receives Approval for Additional Indication of
Anticancer Agent Topotecin® injection**

Tokyo, Japan (December 20, 2013) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today it received supplemental new drug application (sNDA) approval from Japan's Ministry of Health, Labor and Welfare (hereafter MHLW) for Topotecin® injection 40 mg and 100 mg (irinotecan hydrochloride hydrate) for unresectable pancreatic cancer.

Topotecin® injection was developed at the request of the MHLW based on recommendation from the Review Committee for unapproved or off-label use of drugs with high medical needs conducted on March 23, 2012. Daiichi Sankyo submitted the sNDA for this indication in May 2013.

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 A MHLW working group that aims to accelerate the development process for drugs not yet approved in Japan but which are available in Europe and the U.S

Overview

Product name	Topotecin® injection 40 mg and 100 mg
Approval for additional indication	December 20, 2013
Indications and usage	Small cell lung cancer, non-small-cell lung cancer, cervical cancer, ovarian cancer, gastric cancer (inoperable or recurrent), colorectal cancer (inoperable or recurrent), breast cancer (inoperable or recurrent), squamous cell carcinoma, malignant lymphoma (non-Hodgkin lymphoma), pediatric cancer, <u>unresectable pancreatic cancer</u>
Dosage and administration	1. Schedule A is to be used for small-cell lung cancer, non-small-cell lung cancer, breast cancer (inoperable or recurrent), and squamous cell carcinoma. Schedule A or B is to be for cervical cancer, ovarian cancer, gastric cancer (inoperable or

	<p>recurrent), and colorectal cancer (inoperable or recurrent). Schedule C is to be used for malignant lymphoma (non-Hodgkin's lymphoma). Schedule D is to be used for pediatric cancer. Schedule E is to be used for unresectable pancreatic cancer.</p> <p>A: Normally adults are given 100 mg/m² of irinotecan hydrochloride once a day, three or four times, weekly by intravenous infusion; the drug is then discontinued for at least 2 weeks. This constitutes one course of the therapy, and the course is repeated.</p> <p>B: Normally adults are given 150 mg/m² of irinotecan hydrochloride once a day, two or three times, every 2 weeks by intravenous infusion; the drug is then discontinued for at least 3 weeks. This constitutes one course of the therapy, and the course is repeated.</p> <p>C: Normally adults are given 40 mg/m² of irinotecan hydrochloride once a day, for three consecutive days by intravenous infusion. This is repeated at weekly cycles for two to three consecutive weeks; the drug is then discontinued for at least 2 weeks. This constitutes one course of the therapy, and the course is repeated. The dose of the drug for treatment methods A to C may be increased or decreased as is appropriate for the patient's age and symptoms.</p> <p>D: Normally children are given 20 mg/m² of irinotecan hydrochloride once a day, for five consecutive days by intravenous infusion. This is repeated at weekly cycles for two consecutive weeks; the drug is then discontinued for at least 1 weeks. This constitutes one course of the therapy, and the course is repeated.</p> <p>E: Normally adults are given 180 mg/m² of irinotecan hydrochloride once a day by intravenous infusion. The drug is then discontinued for at least 2 weeks. This constitutes one course of the therapy, and the course is repeated.</p> <p>The dose of the drug for treatment methods D and E may be decreased as is appropriate for the patient's age and symptoms.</p> <p>2. When given under Schedule A, B and E, the drug should be mixed, at the time of administration with 500 mL or more of physiologic saline, glucose solution, or electrolyte maintenance solution, and infused over a period of 90 minutes or longer.</p> <p>When using Schedule C, each dose should be mixed, at the time of administration with 250 mL or more of physiologic saline, glucose solution, or electrolyte maintenance solution and infused over a period of 60 minutes or longer.</p> <p>When using Schedule D, each dose should be mixed, at the time of administration with 100 mL or more of physiologic saline, glucose solution, or electrolyte maintenance solution and infused over a period of 60 minutes or longer.</p>
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