

For Immediate Release

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**Daiichi Sankyo Receives Approval in Japan for the Manufacture and Marketing of  
Methemoglobinemia Treatment Methylene Blue Injection 50 mg**

**TOKYO, Japan (January 5, 2015)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has received approval in Japan for the manufacture and marketing of the methemoglobinemia treatment, Methylene Blue Injection 50 mg “Daiichi Sankyo” (JAN: Methylthioninium Chloride Hydrate) for toxic methemoglobinemia on December 26, 2014.

Toxic methemoglobinemia is a toxic disorder in which the methemoglobin concentration in the blood is elevated due to various substances found in drugs, pesticides, etc., causing symptoms such as cyanosis, headache, dizziness, shortness of breath, and loss of consciousness.

Methylene Blue is one of the agents publicly offered for development by the Review Committee on Unapproved Drugs and Indications with High Medical Needs<sup>1)</sup>, set up by the Ministry of Health, Labour and Welfare (MHLW). Daiichi Sankyo acquired sole development and marketing rights for Japan from PROVEPHARM SAS before developing Methylene Blue. In March 2014, Daiichi Sankyo filed an NDA for the manufacture and marketing in Japan for the indication. Daiichi Sankyo received a grant from Pharmaceutical Development Support Center for the development.

In order to collect data on both the safety and efficacy of Methylene Blue, Daiichi Sankyo will conduct a drug use-results survey covering all patients treated with the product during a certain period following its launch.

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 under MHLW that aims to accelerate the development process for drugs not yet approved in Japan but which have been available in Europe and the U.S.

**Product Overview**

Product name	Methylene Blue Injection 50 mg “Daiichi Sankyo”
Generic name (JAN)	Methylthioninium Chloride Hydrate
Indication	Toxic methemoglobinemia
Dosage and administration	<p>For infants older than 3 months, children and adults, administer 1-2 mg/kg of Methylthioninium Chloride Hydrate once intravenously for at least 5 minutes. If symptoms fail to show improvement within 1 hour, the same dosage may be administered again as necessary, up to an accumulated maximum dosage of 7 mg/kg.</p> <p>For infants younger than 3 months, administer 0.3-0.5 mg/kg of Methylthioninium Chloride Hydrate once intravenously for at least 5 minutes. If symptoms fail to show improvement within 1 hour, the same dosage may be administered again as necessary.</p>
Approval date	December 26, 2014