

For Immediate Release

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### **Daiichi Sankyo Launches Methemoglobinemia Treatment Methylene Blue Injection 50mg**

**TOKYO, Japan (March 20, 2015)** - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the launch in Japan of the methemoglobin treatment, Methylene Blue Injection 50mg (JAN: Methylthioninium Chloride Hydrate; approval for manufacturing and marketing obtained December 26, 2014; drug price standard listing February 24, 2015).

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, and received a grant from the Pharmaceutical Development Support Center for its development.

As 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.

<sup>\*1</sup> 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**

Launch date: March 20, 2015

Product name	Methylene Blue Injection 50 mg “Daiichi Sankyo”
Generic name (JAN)	Methylthioninium Chloride Hydrate
Price Listing	50mg 10mL 1 tube: ¥120,382; Drug price standard listing date: February 24, 2015
Indication	Toxic methemoglobinemia
Dosage and administration	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. 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.
Approval date	December 26, 2014
Manufacturing and marketing	Daiichi Sankyo Company, Limited