For Immediate Release

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Daiichi Sankyo Files NDA in Japan for Methaemoglobinaemia Injection Methylene Blue

TOKYO, Japan (March 17, 2014) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that it has filed an NDA for the manufacture and marketing in Japan of the methaemoglobinaemia injection Methylene Blue (INN: Methylthioninium chloride).

Methaemoglobinaemia is a toxic disorder in which the methemoglobin concentration in the blood is elevated due to various chemical substances found in drugs, pesticides etc., causing symptoms such as cyanosis, headache, dizziness, shortness of breath and loss of consciousness. Although Methylene Blue is a highly anticipated treatment for this disorder, there is currently no pharmaceutical grade form of it available in Japan that has been approved by the Ministry of Health, Labour and Welfare.

Methylene Blue is one of the agents publicly offered for development by the Review Committee on Unapproved Drugs and Indications with High Medical Needs[1)] set up by the Ministry of Health, Labour and Welfare. In November 2011, Daiichi Sankyo acquired sole development and marketing rights from PROVEPHARM SAS before developing Methylene Blue. 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 the 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