For Immediate Release

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Daiichi Sankyo Announces Application in Japan for Manufacturing and Sales Approval of Narcotic Analgesic Hydromorphone Hydrochloride

TOKYO, Japan (March 31, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the company has filed an application for the manufacture and sales in Japan of hydromorphone hydrochloride oral formulation (extended-release and immediate-release formulations), a narcotic analgesic.

Hydromorphone hydrochloride is an opiate, narcotic analgesic that has been available outside of Japan for over 80 years. Although it is the standard for pain management for cancer pain treatment according to WHO guidelines, hydromorphone hydrochloride has yet to be approved in Japan.

Hydromorphone hydrochloride is one of the agents publicly offered for development by the Review Committee on Unapproved Drugs and Indications with High Medical Needs*. Daiichi Sankyo decided to develop the drug in 2012, 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 with high medical needs available to patients who are waiting for them to be approved.

* 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.