For Immediate Release

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Daiichi Sankyo and Daiichi Sankyo Espha Obtain Approval in Japan for Supplementary Indication of "Cravit® Tablets, Granules" and "Levofloxacin Tablets, Granules DSEP"

Tokyo, Japan (August 24, 2015) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it and its domestic subsidiary, Daiichi Sankyo Espha Co., Ltd. (hereafter Daiichi Sankyo Espha), have obtained approval for partial changes concerning a supplementary indication of their synthetic broad-spectrum oral antibacterial agents, Cravit® Tablets 250mg and 500mg, Granules 10% (generic name: Levofloxacin hemihydrate), marketed by Daiichi Sankyo, and Levofloxacin Tablets 250mg DSEP and 500mg DSEP, Granules 10% DSEP[*1], marketed by Daiichi Sankyo Espha, for the treatment of pulmonary and other tuberculosis disorders.

In Japan, around 20,000 people are newly diagnosed with tuberculosis each year. Some patients, however, do not continue treatment using first-line drugs because of resistance to or side effects resulting from the drugs. Levofloxacin is the only fluroquinolene-type antibacterial agent approved as an anti-tuberculosis drug in Japan, and it is hoped that it will be an effective treatment taken in combination with other anti-tuberculosis drugs.

This supplementary indication came as a result of Daiichi Sankyo being asked by Japan's Ministry of Health, Labor and Welfare to develop a drug for tuberculosis following a supplementary indication investigation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs[*2]." In addition to this drug providing a new option for patients in need of tuberculosis treatment, as part of its CSR efforts Daiichi Sankyo as a company is committed to making unapproved and off-label drugs available to the patients who are waiting for them.

[*]1 "Levofloxacin Tablets, Granules DSEP" is an authorized generic drug manufactured from the same substance and additives and using the same manufacturing methods as Daiichi Sankyo's "Cravit® Tablets and Granules."

[*]2 A committee set up by the Ministry of Health, Labor and Welfare with the objective of promoting the development of non-approved and off-label drugs whose use are approved in Europe and the U.S. but not yet in Japan.