For Immediate Release

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Daiichi Sankyo and Daiichi Sankyo Espha Submit Supplemental New Drug Application in Japan for "Cravit® Tablets, Granules" and "Levofloxacin Tablets, Granules DSEP"

Tokyo, Japan (October 1, 2014) – Daiichi Sankyo Company Limited (hereafter, Daiichi Sankyo) today announced that it and its domestic generic subsidiary, Daiichi Sankyo Espha Co., Ltd. (hereafter Daiichi Sankyo Espha), have submitted a supplemental New Drug Application (sNDA) in Japan for the synthetic broad-spectrum oral antibacterial agent Cravit® Tablets 250mg and 500mg**,** Granules 10% (generic name: Levofloxacin hemihydrate) and Levofloxacin Tablets 250mg DSEP and 500mg DSEP**,** Granules 10% DSEP[*1] for the treatment of pulmonary and other tuberculosis disorders.

In Japan around 20,000 people are newly diagnosed as tuberculosis each year. Some patients, however, do not continue treatment using first-line drugs because of resistance of bacteria to or drug intolerance. By taking Levofloxacin in combination with other anti-tuberculosis drugs, it is expected that such refractory tuberculosis can be effectively treated.

This application is based on requests from The Japanese Society for Tuberculosis and The Japanese Respiratory Society which were considered by the "Review Committee on Unapproved Drugs and Indication with High Medical Needs[*2]" and which resulted in Daiichi Sankyo being asked by the Ministry of Health, Labor and Welfare to develop a drug for tuberculosis. 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 Daiichi Sankyo Espha obtained a manufacturing and marketing license in Japan for Levofloxacin Tablets, Granules DSEP on August 15, 2014. It 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 is approved in Europe and the U.S. but not yet in Japan.