For Immediate Release

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Daiichi Sankyo Submits Application for Additional Indication of Rifadin® Capsules for Nontuberculous Mycobacterial Disease

Tokyo, Japan (December 15, 2010) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), submitted a supplemental New Drug Application for an additional indication of Rifadin® (rifampicin) 150 mg capsules for nontuberculous mycobacterial (hereafter, NTM) disease based on well-established evidence.

As a result of discussions by the Review Committee on Unapproved Drugs and Indications with High Medical Needs (hereafter the "Review Committee")[1)] held on April 27, 2010, Daiichi Sankyo received a request to develop Rifadin® capsules for a treatment of NTM disease. It was subsequently determined at a Review Committee held on November 10 that an application for an additional indication based on evidence in the public domain[2)] would be submitted.

A preliminary evaluation was conducted on November 29 at the meeting of the Second Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application was permitted.

Rifampicin formulations including Rifadin® have been approved for the NTM disease indication and are used as standard treatments overseas.

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 held by 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

2) Application for a drug commonly known to be medically and pharmaceutically safe and with proven efficacy for which clinical trials can be partly or entirely omitted

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