For Immediate Release

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Challenge to US Levofloxacin PTE has Ended

Tokyo, Japan (October 20, 2010) - Daiichi Sankyo Company, Limited (TSE: 4568; hereafter, Daiichi Sankyo), announced today that the challenge to the levofloxacin patent term extension (PTE) in the United States by generic manufacturer Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively Lupin) has failed.

Lupin challenged the validity of the PTE of the levofloxacin patent (No. 5,053,407) in order to seek the approval of its own generic levofloxacin products. On May 10, 2010, a panel of the United States Court of Appeals for the Federal Circuit affirmed the decision of the U.S. District Court for the District of New Jersey, which held that Daiichi Sankyo's PTE on the patent covering its broad spectrum antibacterial agent, levofloxacin, is valid and would be infringed. Lupin's petition for rehearing by the full Federal Circuit was denied and Lupin's time to appeal to the United States Supreme Court has now run out. This means that Lupin's challenge to the validity of the PTE and the underlying patent in the United States is now at an end.

As a result of this development, generic drug manufacturers, including Lupin, will not be allowed to enter the U.S. market with a generic version of levofloxacin until at least June 20, 2011.

In the United States, Daiichi Sankyo has granted an exclusive license to Johnson & Johnson to manufacture, use, and market pharmaceutical preparations containing levofloxacin, with the right of sublicense. Ortho-McNeil-Janssen Pharmaceuticals, Inc., a subsidiary of Johnson & Johnson, is the exclusive sublicensee for levofloxacin products in the United States and markets levofloxacin products under the trade name LEVAQUIN®.

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