For Immediate Release

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Additional Pediatric Indication for Fentanyl Injection Approved
Japan's First Ever Approval of Physician-led Clinical Trial

Tokyo, August 28 , 2007 – DAIICHI SANKYO COMPANY, LIMITED announced today that its Group company DAIICHI SANKYO PROPHARMA Co., LTD. (President: Masahiro Okabe) obtained approval for an additional pediatric indication for Fentanyl Injection 0.1 mg (Sankyo) and Fentanyl Injection 0.25 mg (Sankyo) as of August 23, 2007. Fentanyl (generic name: fentanyl citrate) will be manufactured by DAIICHI SANKYO PROPHARMA and will be marketed by DAIICHI SANKYO.

Fentanyl Injection is used in analgesia and sedation, as well as in anesthesia and as an anesthetic adjunct, but its use has been contraindicated in Japan for pediatric patients aged two and under because its safety in this group had not been established. However, because of the urgent clinical needs in this area, a physician-led Phase III trial (see note) was conducted in pediatric patients. The trial generated extremely valuable results in this patient group—including newborns and infants—where surgical clinical studies are extremely difficult to perform. On the basis of the results, additional indication in pediatric patients, including infants aged two and under, was filed for approval in September 2006. This is the first physician-led clinical trial that was approved in Japan.

Physician-led domestic clinical trials in pediatric medicine are expected to lead new indications and Fentanyl will satisfy the clinical needs as Japan's first pediatric opioid with dosage and administration determined.

Note: Amendments to the Pharmaceutical Affairs Law in July 2003 enabled investigators

(physicians) to lead the implementation of clinical studies, based on the Ministerial Ordinance for Good Clinical Practice (GCP).