For Immediate Release

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Daiichi Sankyo receives approval in Japan to manufacture and market Cravit® intravenous injections

Tokyo, Japan (October 27, 2010) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), today announced that it has received approval in Japan to manufacture and market new formulations of Cravit® (generic name: levofloxacin hydrate). The fluoroquinolone intravenous anti-bacterial agent comes in 500mg/100ml IV bags and 500mg/20ml injections (hereafter, Cravit® IV).

Cravit® IV is administered once daily according to PK-PD theory (see Note 1 below). It is highly efficacious against major pathogens and atypical bacteria that are not indicated for treatment with penicillin-, cephem- and carbapenem-based preparations. It is classified as a respiratory quinolone (see Note 2 below) suited to treat respiratory tract infections. The treatment has already been approved in 120 different countries and territories, and has been very well received.

In Japan, orally administered 100mg Cravit® tablets were approved for sale in December of 1993, and in July of 2009, the once-daily administration with 500mg Cravit® was approved in line with the world standard dosage regimen. Now, Daiichi Sankyo has further expanded treatment options with the addition of Cravit® IV, and it will continue to contribute to the development of improved treatments for infectious diseases by promoting the adoption of this new formulation.

Note 1: PK-PD theory

This is a scientifically proven concept for designing the optimal administration of anti-bacterial agents. This anti-bacterial efficacy and safety assessment concept combines pharmacokinetics (PK), which shows how anti-bacterial agent concentration changes within the human body, and pharmacodynamics (PD), which considers the actions of anti-bacterial agents within organisms.

Note 2: Respiratory quinolone

Respiratory quinolones are fluoroquinolones which have a high degree of efficacy against many bacterial pathogens including *S. pneumoniae*, the major cause of bacterial respiratory infections. They also have been shown to be effective against many atypical bacteria (such as *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*) that are not susceptible to cephems, carbapenems and penicillins.

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