

For Immediate Release

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Daiichi Sankyo Launches Cravit® Intravenous Injections

Tokyo, Japan (January 11, 2011) - Daiichi Sankyo Company, Limited (TSE, 4568; hereafter, Daiichi Sankyo) today announced the launch in Japan of Cravit® Intravenous Injections (hereafter, Cravit IV), a new formulation of its fluoroquinolone intravenous anti-bacterial agent, Cravit (generic name, levofloxacin hydrate; approval for manufacture and marketing, October 27, 2010; NHI drug price listing, December 10, 2010), available in 500mg/100mL IV bags and 500mg/20mL injections.

In accordance with PK/PD theory^{*1}, a dosage of Cravit IV can be administered once-daily to combat atypical bacteria that show resistance to cepheems, carbapenems and penicillins. A respiratory quinolone^{*2} is a fluoroquinolone indicated for the treatment of respiratory tract infections. Cravit has already been approved in 120 countries and regions and is regarded highly around the world.

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 PK/PD models and has become popular as a one time per day anti-bacterial treatment. Daiichi Sankyo has further expanded therapeutic options with the addition of Cravit IV, and it will continue to contribute to the improvement of treatments for infectious diseases through the promotion of the new formulation.

***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 efficacy and safety of anti-bacterial agents in the body.

*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 show resistance to cepheems, carbapenems and penicillins.

Product outline

(Date of launch: January 11, 2011)

Classification	Fluoroquinolone intravenous anti-bacterial agent
Product name(s)	Cravit® 500mg/100mL bags Cravit® 500mg/20mL injections
Generic name	levofloxacin hydrate
Drug Price	Cravit 500mg/100mL bags: 5,326 yen per kit Cravit 500mg/20mL injections: 5,222 yen per bottle (NHI listing December 10, 2010)
Efficacy	<p>Strains (21)</p> <p>Levofloxacin-susceptible strains of <i>Staphylococcus</i> sp., <i>Streptococcus</i> sp., <i>Streptococcus pneumoniae</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Bacillus anthracis</i>, <i>Escherichia coli</i>, <i>Salmonella typhi</i>, <i>Salmonella paratyphi</i>, <i>Klebsiella</i> sp., <i>Enterobacter</i> sp., <i>Serratia</i> sp., <i>Yersinia pestis</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, <i>Acinetobacter</i> sp., <i>Legionella</i> sp., <i>Brucella</i> sp., <i>Francisella tularensis</i>, <i>Coxiella burnetii</i>, <i>Chlamydomphila pneumoniae</i>, and <i>Mycoplasma pneumoniae</i></p> <p>Indications (9)</p> <p>Pneumonia, secondary infections of chronic respiratory disease, typhoid fever, paratyphoid fever, anthrax, brucellosis, plague, tularemia, Q fever</p>
Dosage	For adults, a once-daily 500mg dosage of Levofloxacin administered intravenously in about 60 minutes.
Remarks	Manufacture and marketing: DAIICHI SANKYO Co., Ltd.

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