For Immediate Release

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Daiichi Sankyo Obtains Approval in Japan for Supplementary Indication of New Quinolone Antibacterial Injection, "Cravit® Intravenous Drip Infusion"

Tokyo, Japan (September 24, 2015) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has obtained approval for partial changes concerning a supplementary indication of their new quinolone antibacterial injections, Cravit® Intravenous Drip Infusion Bag 500mg/100mL and Cravit® Intravenous Drip Infusion 500mg/20mL (generic name: Levofloxacin Hydrate) to treat bacterial infections of urology, surgery, and gynecology.

These injections are broad-spectrum antibiotics for single-dose daily administration against Gram-positive and -negative bacteria and atypical pathogens. They will be indicated for the treatment of newly approved conditions in addition to respiratory infections, thereby increasing the indications (excluding peritonitis for which an oral agent is not indicated) for switch therapy from injection to oral medicine with the same active ingredient.

Daiichi Sankyo aims to contribute further in the field of medicine by providing new therapeutic options to patients and medical professionals through its Cravit® Intravenous Drip Infusion injections.

Product Overview

Product Name	Cravit [®] Intravenous Drip Infusion Bag 500mg/100mL Cravit [®] Intravenous Drip Infusion 500mg/20mL
Generic name (JAN)	Levofloxacin Hydrate
Approval date for partial modification	September 24, 2015
Indication (additional content underlined)	<bacterial species=""> Levofloxacin-susceptible Staphylococcus sp., Streptococcus sp., Streptococcus pneumoniae, Enterococcus sp., Moraxella (Branhamella) catarrhalis, Bacillus anthracis, Escherichia coli, Salmonella typhi, Salmonella paratyphi, <u>Citrobacter sp.</u>, Klebsiella sp., Enterobacter sp., Serrati sp., <u>Proteus sp., Morganella morganii, Providencia sp.</u>, Yersinia pestis, Haemophilus influenzae, Pseudomonas aeruginosa, Acinetobacter sp., Legionella sp., Brucella sp., Francisella tularensis, <u>Peptostreptococcus sp., Prevotella sp., Coxiella burnetii, Chlamydia trachomatis,</u> Chlamydia pneumoniae, and Mycoplasma pneumoniae</bacterial>
	<indications> Secondary infections after trauma, burns, and surgical wounds, pneumonia, secondary infections in chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute and chronic prostatitis), epididymitis, peritonitis, cholecystitis, cholangitis, typhoid, paratyphoid, intrauterine infection, uterine adnexitis, bacillus anthracis, brucellosis, plague, tularemia, and Q fever</indications>