SYNOPSIS

Name of Sponsor/Company	Daiichi Sankyo Co., Ltd.
Name of Finished Product	CRAVIT ® INTRAVENOUS DRIP INFUSION
Name of Active Ingredient	Levofloxacin
Title of Study	Clinical study of DR-3355 injection in patients with acute bacterial prostatitis or acute epididymitis
Investigators	
Study Centre(s)	6 sites
Publication (reference)	None
Studied Period	Date of obtaining first consent: July, 2012 Date of last observation: February, 2013
Phase of Development	Phase 3
Objectives	The purpose of this study is to evaluate efficacy and safety of DR-3355 injection on acute bacterial prostatitis or acute epididymitis.
Methodology	Multicenter, Open-label study
Number of Patients (planned and analyzed)	Planned: 18 subjects Registered: 18 subjects Analyzed: Analysis set of efficacy (PPS) 13 subjects Analysis set of safety 18 subjects
Diagnosis and Main Criteria for Inclusion	Diagnosis: Acute bacterial prostatitis, Acute bacterial epididymitis, Acute chlamydial epididymitis Inclusion criteria: 1) Patients with age of 20 and over at the time of obtaining informed consents. 2) Patients with symptoms of acute prostatitis or acute epididymitis. 3) Patients who meet the criteria for pyuria and have bacteria in the urine 4) Patients who require an injection treatment. (any of the following symptoms: pain and swelling of the epididymis, temperature of 38 degrees or more, nausea or vomiting, dehydration, suspicion of bacteremia, urine flow failure, anorexia, diarrhea) Exclusion criteria: 1) Patients who have indwelling catheter in the urinary tract.

	2) Patients whose urinary tract is routed through bowels. 3) Patients who had a prostate biopsy immediately prior to enrollment. 4) Patients whose symptoms have shown improvement due to the administration of other antibacterial agents within 7 days prior to the test drug administration. 5) Patients with infectious diseases for whom levofloxacin did not work obviously, or patients having fungus that has been detected in a bacteria test prior to this trial. 6) Patients with urinary tract infection other than target diseases (acute prostatitis or acute epididymitis). 7) Patients who have received levofloxacin within 30 days prior to the test drug administration. 8) Patients with a history of allergy/severe adverse effects to quinolone antibacterial agents. 9) Patients with a history of seizure/epilepsy/disturbance of consciousness. 10) Patients who have difficulty in judging the efficacy of the study drug (including patients suffering from progressive cancer or other underlying diseases which prevent the evaluation). 11) Patients with severe hepatic impairment, renal impairment, or cardiac impairment. 12) Patients who require prohibited concomitant medications or treatments in this study. 13) Patients who participated in any other clinical trials within 30 days prior to this trial. 14) Patients who have participated in the clinical trial of DR-3355 injection previously, and have been treated with the test drug. 15) Other patients who are judged to be inappropriate by the investigator
Test Product, Dose and Mode of Administration, Batch Number	Test product (batch number): DR-3355inj (D3355I0H11T01A) Levofloxacin tablet (D3355F0S11T01A) Dosage and administration: Intravenous administration of DR-3355inj at 500 mg, once daily

	Oral administration of levofloxacin at 500 mg, once daily
Duration of Treatment	14 to 21 days DR-3355inj is administered for three days at least, and then, is switched to levofloxacin tablet at the discretion of the investigator in accordance with clinical symptoms (defervescence and/or improvement). Duration of administration including oral is 14 to 21 days.
Reference Therapy, Dose and Mode of Administration, Batch Number	None
Criteria for Evaluation	Primary: Bacteriological efficacy at the test of cure Secondary: 1) Bacteriological and clinical efficacy, and bacteriological efficacy of different types of bacteria at the end of injection treatment 2) Clinical efficacy and bacteriological efficacy of different types of bacteria at the test of cure 3) Bacteriological and clinical efficacy at the test of recurrence
Statistical Method	Primary: The point estimate of the bacteriological efficacy rate and the two-sided 95% confidence interval are calculated by diagnosis. Secondary: The point estimate of the bacteriological/clinical efficacy rate and the two-sided 95% confidence interval are calculated by diagnosis.
Summary - Conclusion	Efficacy summary: The primary endpoint was bacteriological efficacy rate at the test of cure in PPS. The efficacy rate was 83.3% (5/6) in patients with acute bacterial prostatitis, and 83.3% (5/6) in patients with acute bacterial or chlamydial epididymitis. The clinical efficacy rate at the test of cure was 83.3% (5/6) in patients with acute bacterial prostatitis, and 66.7% (4/6) in patients with acute bacterial or chlamydial epididymitis. Safety summary: The incidence of adverse events was 38.9% (7/18) in the whole period, and adverse events that occurred in 2 or

	more were not reported. One subject was discontinued administration of investigational drug by mild contact dermatitis of adverse event . Incidence of adverse drug reactions was 22.2% (4/18) in the whole period. All adverse events were mild in severity, all subjects who had adverse events were recovered with or without medical treatments. Conclusion: From these results, DR-3355inj (including switch therapy to levofloxacin oral agent) is useful for treatment of acute bacterial prostatitis and acute bacterial or chlamydial epididymitis and there is no important problem in the safety.
Date of Report	July 8, 2014