Synopsis

(1) Sponsor	Toyama Chemical Co., Ltd.
(2) Brand name	Pasil intravenous drip infusion 300 mg Pasil intravenous drip infusion 500 mg Pasil intravenous drip infusion 1000 mg
(3) Generic name	Pazufloxacin mesilate
(4) Title of the study	Specific post-marketing surveillance of pazufloxacin (Pasil) Clinical efficacy and safety of pazufloxacin administered at a dose of 1,000 mg twice daily
(5) Name of principal investigator	—
(6) Number of medical institutions	82
(7) Publication	Totsuka K, Watanabe S and Kushimoto S: Postmarketing surveillance for high-dose of injectable pazufloxacin mesilate 1,000 mg twice daily. Jpn. J. Chemother. 2015; 63: 473-89
(8) Duration of the study	Nov 2010 – Mar 2013
(9) Study phase	Other
(10) Objectives of the study	To evaluate the effectiveness and safety in patients to whom Pasil 2000 mg is administered for sepsis, severe and/or intractable respiratory tract infections (pneumonia, secondary infection of chronic respiratory diseases), or pneumonia caused by *Streptococcus pneumoniae* (*S. pneumoniae*).
(11) Study design	Post-marketing surveillance study Patients were registered by the patient registration center system. Observational study
(12) Number of cases	342
(13) Inclusion criteria	1. Age: 15 years of age and older 2. Patient is administered 2000mg/day in two divided doses 3. Patient has never been registered in this study
(14) Dosage and administration	At the daily dose of 2000 mg as pazufloxacin in two divided doses by intravenous drip infusion
(15) Duration of therapy	—
(16) Control, dosage and administration	—
(17) Endpoint	Effectiveness (evaluated by investigator): effective, not effective, indeterminable Bacteriological effect: disappearance/presumptive disappearance, decrease or partially disappearance, microbial substitution, continuation, unevaluable Safety: Adverse events during the observation period
(18) Statistical methods	Stratified analysis was conducted to find factor affecting in effectiveness and safety, used Chi-squared test, the significance level was set at 5% on both sides. If there were the cells expected value ware less than 5, used Fisher's exact probability test.
(19) Summary and conclusion	The effective rate was 83.8% (244/291). The effective rate of *S. pneumoniae* infection cases was 84.4% (27/32), bacteriological effectiveness against *S. pneumoniae* was 100% (10/10). The incidence of adverse drug reactions was 17.84% (61/342), and the incidence of injection site reactions that were intensively investigated is 7.89% (27/342).
(20) Date of report	Feb 21, 2018