Synopsis

(1) Sponsor	Toyama Chemical Co., Ltd.
(2) Brand name	Geninax Tablets 200mg
(3) Generic name	Garenoxacin Mesilate Hydrate
(4) Title of the study	Specific post-marketing surveillance of garenoxacin (Geninax) Clinical efficacy and safety of garenoxacin in the treatment of legionella pneumonia
(5) Name of principal investigator	—
(6) Number of medical institutions	24
(7) Publication	—
(8) Duration of the study	May 2008 - April 2012
(9) Study phase	Other
(10) Objectives of the study	To evaluate the effectiveness and safety of Geninax tablets for Legionella pneumonia in daily clinical practice.
(11) Study design	Post-marketing surveillance study. Data of the patients received Geninax was collected retrospectively, from the patients with Legionella pneumonia registered the Japanese Society of Chemotherapy Legionella committee.
(12) Number of cases (protocol/analysis)	Protocol: more than 20 Analysis: 36
(13) Inclusion criteria	1. Cases in which pathogen, antigen of pathogen, gene of pathogen or antibody of pathogen are detected for diagnosis. 2. Regardless of sex 3. Cases which are able to be followed up
(14) Study drug, dosage and administration	400 mg once daily, oral administration
(15) Duration of therapy	—
(16) Control, dosage and administration	—
(17) Endpoint	Effectiveness (evaluated by investigator): Effective on therapy: effective, not effective, unevaluable Preventive effect of infection relapse: effective (non-relapse), not effective (relapse), unevaluable Safety: Adverse events during the observation period
(18) Statistical methods	Effectiveness: The effective rate in “effective on therapy” and “preventive effect of infection relapse” is calculated. Safety: The incidence of adverse drug reactions with each patients background.
(19) Summary and conclusion	The effective rate was 100% (18/18) in “effective of therapy”, 9/9 in a first-line treatment and 9/9 in a second or later-line treatment. The effective rate was 100% (14/14) in “prevention effect of infection relapse”. The incidence of adverse drug reactions was 19.44% (7/36), hepatic function abnormal in 8.33%, anaemia, tongue coated, liver disorder, drug eruption, rash, alanine aminotransferase increased, prothrombin time prolonged and white blood cell count decreased in 2.78%. Those were not serious.
(20) Date of report	February 21, 2018