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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00261105
		Study Code:	HMR3647A_4026
Generic drug name:	Telithromycin	**Date:**	01/Oct/2007

Title of the study:	An open, multi-center phase IV trial of the efficacy and safety of Ketek® (telithromycin) 800 mg once daily in treating outpatients with mild to moderate Community Acquired Pneumonia, Acute Exacerbations of Chronic Bronchitis and Acute Sinusitis.		
Investigator(s):	Chang Tae Young, The otorhinolaryngology department, Inha University Hospital		
Study center(s):	12 centers, Korea		
Publications (reference):	Not applicable		
Study period: Date first **patient** enrolled: 14- Feb-2005 Date last **patient** completed: 18- Oct- 2005		**Phase of development:** IV	
Objectives:	Primary : To evaluate clinical efficacy of , Ketek® (telithromycin) in the treatment of community acquired respiratory tract infections in outpatients: Community Acquired Pneumonia (CAP), Acute Exacerbation of Chronic Bronchitis (AECB) and Acute Sinusitis (AS). Secondary : 1) Further assess the efficacy of Ketek® (telithromycin) with the rate at which additional antibacterial were prescribed to treat the primary infection; the rate of hospitalization due to a complication of the primary infection and assessment of bacteriological data, chest X-ray and sinus X-ray if available. 2) Evaluate the safety of Ketek® (telithromycin) through Adverse Event (AE) and Serious Adverse Event (SAE) 3) Health-economic data		
Methodology:	Open, Multi-center, Phase IV		
Number of subjects:	120	Randomized:	Treated: 122
Evaluated:	118	Safety:	122

Diagnosis and criteria for inclusion:	Subjects who met all the following criteria were considered to be eligible for this study: Basic Requirements: 1) Outpatients (male and female) > 18 years old. 2) One of the followings should be fulfilled; Mild to moderate CAP, AECB, AS 3) Written informed consent obtained	
Investigational product: Dose: Administration:	Ketek 800mg per day Per oral	
Duration of treatment: - In the case of CAP: 800 mg once daily for 7 to 10 days -In the case of AECB or AS: 800 mg once daily for 5 days		**Duration of observation:**
Reference therapy:	Not applicable	
Criteria for evaluation:		
Efficacy:	1) Clinical Outcome (Global Assessment by the participating physicians) 2) Rate at which additional antibacterial were prescribed to treat the primary infection 3) Rate of hospitalisation due to a complication of the primary infection 4) Assessment of chest X-ray and sinus X-ray if available.	
Safety:	Adverse Event (AE) and Serious Adverse Event (SAE) reported	
Statistical methods:	1) Efficacy population (1) Intent- To- Treat (ITT) population consists of all patients who were diagnosed as AECB, CAP, AS and who received at least one dose of the study medication. (2) Per Protocol (PP) population consists of ITT population without major protocol violations. They were analysed according to the diagnosis group. 2) Safety population: It consists of all patients who had received at least one dose of the study medication. (ITT population)	

Summary:	A total of 122 patients were enrolled and received open label treatment with telithromycin. 118 subjects received study medication and 4 subjects diagnosed as AS did not take study medication. PP population eligible for clinical evaluation was totally 83.
Efficacyresults:	The primary efficacy analysis was clinical outcome rate at the post therapy. The Clinical cure rate of Telithromycin was 85.6 % (101/118 subjects) The lower and upper bounds of the two sided 95% confidence interval (CI) were 79.3% and 91.9% respectively. In the PP population, the results of the analyses of clinical cure rate showed a satisfactory outcome rate of 89.2% (75/119 subjects). The lower and upper bounds of the two sided 95% confidence interval (CI) were 82.5% and 95.8% respectively. The cure rates in each disease were 85.9% (67 patients) in AS, 82.9% (29 patients) in AECB. In the case of CAP, all the patients were cured but the number of subjects was too small to compare its cure rate with other disease groups. The PP population analyses showed similar results. The secondary efficacy analysis, bacterial examination, endoscopy and evaluation of clinical symptoms and signs, were performed and compared among baseline, visit 2 and visit 3 for each indications. In bacterial examinations, pathologic organisms were found in one patient in CAP, 6 patients in AS at baseline visit, but all of them were not found at visit 3. Single strain of "Corynebacterium Xerosis" was found in one patient of CAP at visit 3. Endoscopic exam showed 'improvement' in 35 patients (51.5%), and 'recovered as before' in 30 patients (44.1%). In other words, 95.6% showed positive results. The evaluation of clinical symptoms and sign showed that showed improvement in ITT and PP populations with decreased severity or disappearance of symptoms or signs.
Safety results:	The rate of adverse events possibly related with treatment was 14.4% (17/118) in the safety population. Most adverse events were mild or moderate in intensity. Treatment-Emergent Adverse Events (TEAEs) were reported in a total of 5 (4.2%). The most common TEAEs involved the gastrointestinal system and respiratory system. Serious adverse event (Maxillary squamous cell carcinoma) was concluded to be unrelated to the study drug, and none of them resulted in the treatment discontinuation.
Conclusions:	The efficacy of Telithromycin (800mg) once daily for 5~10 days showed that it was safe and generally well tolerated. Therefore, Telithromycin 800mg for 5~10 days is considered to be an effective, safe and convenient in the treatment for Acute Exacerbation of Chronic Bronchitis, mild to moderate Community Acquired Pneumonia, Acute Sinusitis.
Date of report:	16 Jun 2006