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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**Clinicaltrials.gov Identifier:**	NCT00288223
Generic drug name:	telithromycin	**Study Code:**	HMR3647A_4022
		Date:	28 November 2008

Title of the study:	Multi-center, non-comparative phase IV study evaluating the efficacy and safety of telithromycin (800 mg/day, 5 days) in the treatment of acute exacerbation of chronic bronchitis in adults		
Investigator:	Prof. Dr. Sema Umut		
Study center:	Istanbul University, School of Medicine of Cerrahpaşa, Department of Chest Disease, Istanbul, TURKEY		
Publications (reference):	None		
Study period: Date first patient enrolled: 04-JAN-2006 (Date of first signed informed consent) Date last patient completed: 05-JAN-2007 (Date of last patient last visit) Date enrollment period stopped: DEC-2007			Phase of development: IV
Objectives:	Primary: To demonstrate the efficacy of telithromycin treatment (800 mg/day, for 5 days) during acute exacerbation of chronic bronchitis in Visit 2 (Day12-Day19). Secondary: • To assess the long term efficacy of telithromycin clinically by phone [in Visit 3 (Day25-Day35)] • To assess the safety of telithromycin		
Methodology:	Multi-center, non-comparative phase IV study		
Number of patients:	Planned: 100	Randomized: 54	Treated: 54
Evaluated:	Efficacy: 49	Safety: 54	Pharmacokinetics: NA
Diagnosis and criteria for inclusion:	• Outpatients, male or female, aged 35 years or older, • Patients with a documented history of chronic bronchitis, characterized by excessive sputum production for most days of at least three months on 2 consecutive years • The presence of at least two of the following Anthonisen criteria during acute exacerbation of their disease: - Increased severity of dyspnea - Increased expectoration volume, - Increased expectoration purulence • Patients who has given written informed consent.		

Investigational product: Dose: Administration:	Telithromycin 800 mg/day (once a day) Oral
Duration of treatment: 5 days	Duration of observation: 25-35 days (follow-up phone call) after the initiation of the study drug.
Reference therapy:	There were no reference treatment / therapies
Criteria for evaluation:	
Efficacy:	Primary: Clinical success rate in TOC visit (cure + improvement) (D12-19). Secondary: Clinical success rate (%) in sub-populations under risk in TOC visit Clinical success rate (%) in follow up visit (D25-35) Re-infection rates (%) Percent of treatment discontinuation rate Compliance rate (%)
Safety:	Safety assessment was performed on the basis of serious and non-serious adverse events.
Statistical methods:	The study was stopped by sponsor decision before planned patient population was enrolled. The formal demographics, efficacy and safety data evaluation was performed by using descriptive statistical methods.
Summary	
Efficacy results	The three major symptoms of AECB, cough, dyspnea and sputum discharge which were recorded during the initial enrollment visit (V1), Test of Cure Visit (V2) and Follow-up visit (V3) were significantly decreased in severity ($p < 0.01$) with telithromycin treatment for 5 days, at a dosage of 800 mg/day.
Safety results:	During study two serious adverse event was reported for the safety population (n=54). One serious event was reported as a hospitalization for cataract operation. However, upon follow-up evaluation, it was revealed that the cataract operation was previously planned before the study enrollment so the SAE rating was suspended by the study sponsor. The second serious adverse event was recorded as a hospitalization due to exacerbation of Chronic Obstructive Pulmonary Disease. A total of 8 adverse events were recorded in 6 patients during the study period. Study treatment was permanently discontinued in one case due to severe diarrhea, other adverse events did not require any action. Four of the 8 adverse events were interpreted as related to study drug (gastritis, disease recurrence and patient, diarrhea in two cases) and the others not related. The most common adverse events were; diarrhea and disease recurrence.
Date of report:	13 October 2008