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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00546676
		Study Code:	HMR3647A_4018
Generic drug name:	Telithromycin	**Date:**	13/Nov/2007

Title of the study:	A Canadian multicenter, prospective, open label, non-comparative Phase IV study of the effectiveness and safety of oral telithromycin, 800 mg once daily in the treatment of either community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB) in ambulatory adult patients in a community-based setting.
Investigator(s):	Karl Weiss, MD Hôpital Maisonneuve-Rosemont 5145 boul. de l'Assomption Montréal, Qc. Canada H1T 2M4
Study center(s):	53 sites throughout Canada
Publications (reference):	No publication

Study period: Date first patient/ enrolled: 05-Mar-2004 Date last patient/completed: 07-Dec-2004	**Phase of development:** IV

Objectives:	The primary objective of this study was to determine the clinical effectiveness of telithromycin in the treatment of either community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB) in a large population of ambulatory adult patients in a community-based setting. The secondary objectives of this study were: • To determine the speed of symptom resolution • To define the safety of telithromycin • To assess the following health economic parameters: - Healthcare resource utilization - Lost productivity
Methodology:	This was multicenter, prospective, open label, non-comparative phase IV study enrolling patients suffering from either CAP or AECB. CAP patients were treated for 10 days with telithromycin and AECB patients were treated for 5 days. In both instances, the dose of telithromycin was 800 mg OD. There was a pre-therapy visit (Visit 1) for all patients and two post-therapy visits. Visit 2 was performed on days 12 to 17 for CAP patients and days 7 to 12 for AECB patients. Visit 3 or late post-therapy

	visit was performed on days 40 to 45 for CAP patients on days 19 to 26 for AECB patients.		
Number of patients::	Planned: 600 (400 AECB and 200 CAP)	Randomized: Not Applicable	Treated: 171 (70 CAP and 101 AECB)
Evaluated:	Efficacy: Clinical cure rates based on the resolution of signs and symptoms	Safety: Treatment emergent adverse events (TEAEs)	
Diagnosis and criteria for inclusion:	Male and female patients = 18 years who fulfilled the clinical diagnostic criteria for outpatient treatment of one of the two following diseases: CAP • Pneumonia confirmed by a new pulmonary infiltrate upon x-ray • At least 3 of the following signs or symptoms of infection: fever = 38°C, cough, chest pain, sputum production, rales, dyspnea, malaise and/or headache AECB • Documented medical history of chronic bronchitis in patients over the age of 40 and presenting an FEV_1 < 80% of the predicted value in the last 36 months • At least 2 of the following clinical symptoms: increased sputum purulence, increased dyspnea and/or increased sputum production		
Investigational product: Dose: Administration:	Telithromycin 800 mg OD		
Duration of treatment: 10 days for CAP and 5 days for AECB		**Duration of observation:** Up to 45 days for CAP and 26 days for AECB	
Reference therapy:	Not Applicable		
Criteria for evaluation:	The current report is an abbreviated report, and as such, only the safety results are being presented in full. TEAEs were evaluated, and analyzed using descriptive statistics. A TEAE is defined as any new adverse event (AE) or any existing AE which worsened following the first dose of study drug until 7 days after the last dose of study drug.		
Statistical methods:	Descriptive statistics using means, medians, standard deviations, and ranges for continuous data and numbers of patients and percentages for categorical data		

Summary:

From the 174 patients screened, there were 171 treated patients comprising the safety population in which there were 70 CAP and 101 AECB patients.

Study Completion

Characteristic	Statistic	CAP	AECB
Number of patients	Number	70	101
Withdrawn	Number (%)	5 (7.1)	6.(5.9)
Duration of study drug (days)	Mean (SD) Median Range	10.2 (2.27) 10 1 – 25	5.3 (1.30) 5 1 – 15
Duration of follow-up (days)	Mean (SD) Median Range	47.3 (17.82) 43 23 – 161	31.9 (72.95) 23 2 – 752
Reason for withdrawal			
Adverse event	Number (%)	0 (0.0)	2 (33.3)
Lost to follow-up	Number (%)	4 (80.0)	1 (16.7)
Screen failure	Number (%)	1 (20.0)	3 (50.0)

Demography

Characteristic	Statistic	CAP	AECB
Number of patients	Number	70	101
Age (years)	Mean (SD) Median Range	58.3 (16.55) 59 26 – 88	62.2 (12.78) 64 27 – 84
Males	Number (%)	38 (54.3)	50 (49.5)
Race			
White	Number (%)	58 (82.9)	82 (81.2)
Asian	Number (%)	10 (14.3)	12 (11.9)

Eleven treatment adverse events (TEAEs) were reported by 8 (11.4%) patients. No treatment emergent adverse event was reported in more than one CAP patients. There were four possibly related TEAEs reported by 3 (4.3%) CAP patients, each by one patient. They were blurred vision, abdominal pain, diarrhea, exacerbated dyspnea. There was an unrelated serious TEAE, hemorrhagic diathesis, reported on day 6 of treatment for one patient who recovered without sequelae. There was no TEAE leading to discontinuation of study drug in any CAP patient.

Twenty-six (26) TEAEs were reported by 21 (20.8%) AECB patients There were 19 possibly related TEAEs reported by 15 (14.9%) patients.

The table below lists the events reported by more the one patient.

System Organ Class/Preferred Term	All TEAEs	Possibly Related TEAEs
Number of patients	101	101
Eye disorders	2 (2.0%)	2 (2.0%)
Blurred vision	2 (2.0%)	2 (2.0%)
Gastrointestinal disorders	9 (8.9%)	6 (5.9%)
Blurred vision	6 (5.9%)	4 (4.0%)
Diarrhea	4 (4.0%)	3 (3.0%)
General disorders	3 (3.0%)	3 (3.0%)
Chest pain	2 (2.0%)	2 (2.0%)
Infections and infestations	3 (3.0%)	3 (3.0%)
Bronchitis	2 (2.0%)	2 (2.0%)
Nervous system disorders	4 (4.0%)	1 (1.0%)
Headache	2 (2.0%)	0 (0.0%)

There was no serious TEAE reported by any AECB patient. Two patients discontinued study drug for blurred vision, disorientation, and chest pain and for restlessness and asthenia both on day one of study medication.

Date of report: 17-Oct-2007