These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00544180
		Study Code:	RISED_L_01686
Generic drug name:	Risedronate	**Date:**	17/Oct/2007

Title of the study:	**ROSPA**: Record On Satisfaction of Patients with Actonel 35 mg Once A Week
Investigator(s):	NA
Study center(s):	Wolfson Medical Center, Israel Rambam Medical Center, Israel Beilinson Hospital, Rabin Medical Center, Israel
Publications (reference):	1. Who are candidates for prevention and treatment for osteoporosis, Osteoporosis Int. 1997; 7:16 2. Osteoporosis/ Epidemiolgy, diagnosis and treatment. M.Masud Iqbal. Southern Medical Journal. Jan 2000. Vol 93,1 3. Joens G. Symptomatic fracture incidence in elderly men and women. The Dubbo Osteoporosis Epidemiology Study (DOES). Osteoporosis Int 1994; 4:277-82 4. Lindsay R. Estrogen deficiency in Riggs BL et al. osteoporosis: Etiology, diagnosis and Management. 2nd ed. Philadelphia, Pa: Lippincott. Raven Publishers 1995: 133-160 5. Treatment of postmenopausal osteoporosis. R. Eastell. NEJM 1998; Vol 338: 11: 736-746 6. Lombas et al. J Bone Mineral Res 2000: 15: M406 7. Roldan et al. ASBMR 2001; abstract SU 411 8. Ettinger et al. J Managed Care Pharm, 1998; 4:488 9. Lewiecki. ASBMR 2001 10. Harris et al. Jama, 1999; vol 282: No.14 11. Reginster et al. Osteoporos Int (2000) 11:83-91 12. Bensen et al. WCO Lisbon 2002 13. Watts et al. J Bone Mineral Res. 2000; 16(1): S407 14. Watts et al: WCO 2002

Study period:	**Phase of development:**
Date first **patient/subject** enrolled: 25-May-2005	Phase IV
Date last **patient/subject** completed: 06-Sep-2006	

Objectives:	To determine the satisfaction of subject with Actonel 35 mg Once a Week in the treatment of postmenopausal osteoporosis. To document the safety of Actonel 35 mg Once a Week in routine medical practice.		
Methodology:	The subject will be treated with Actonel 35 mg Once A Week by prescription from the physician (investigator) as in usual practice.		
Number of patients/subjects:	Planned: 500	Randomized: 70	Treated: 7
Evaluated:	- Efficacy: The investigator will record at end of therapy his overall assessment of efficacy and safety of Actonel 35 mg Once A Week. - Subjects will be asked to complete at end of the treatment a 3-item patient satisfaction questionnaire. - The tolerability of Actonel 35mg will be evaluated by the record of adverse events, if any that might occur during the course of the study.	Safety: NA	Pharmacokinetics: NA
Diagnosis and criteria for inclusion:	Postmenopausal ambulatory women > 55 and <80 years of age who have a clinical presentation appropriate for treatment of established osteoporosis based on the investigator's clinical judgment (a T-score for BMD (DEXA) of lumbar spine or femoral neck = - 2.5 from an assessment performed at screening or within 24 weeks prior to the screening visit or evidence of previous vertebral fracture). Exclusion criteria: - History of Cancer: Basal Cell or Squamous Cell carcinoma-documented 6-month remission - Diagnosis of hypocalcemia, hyperparathyroidism, hyperthyroidism		
Investigational product: Dose: Administration:	Actonel (Risedronate sodium) 35 mg Tablet (oral)		
Duration of treatment: For the purposes of this study, the period of observation extends from the time the subject starts therapy until the end of therapy at 6 months or earlier.	**Duration of observation:**		

Reference therapy: Dose: Administration:	NA NA NA
Criteria for evaluation:	- The investigator will record at end of therapy his overall assessment of efficacy and safety of Actonel 35 mg Once A Week. - Subjects will be asked to complete at end of the treatment a 3-item patient satisfaction questionnaire. - The tolerability of Actonel 35mg will be evaluated by the record of adverse events, if any that might occur during the course of the study.
Safety: **Statistical methods:**	Adverse events reported by the patient/subject or noted by the investigator. Statistical analysis of all data collected in this study will be descriptive. Investigators participating in this RECORD will be informed of the results once the Final Report has been written up.
Summary:	The trial was terminated due to lack of compliance with GCP regulations.
Efficacy results:	NA: this trial was prematurely discontinued and the data generated will not be used, due to lack of compliance with GCP regulations
Safety results:	NA: this trial was prematurely discontinued and the data generated will not be used, due to lack of compliance with GCP regulations
Date of report:	17-Sep-2007