

Protocol Summary

Name of Sponsor: Takeda Pharmaceutical Company Limited	Drug Under Study (r-INN): ATL-962
Title of Protocol: A phase 3 confrimatory study of ATL-962	
Study Number: ATL-962/CCT-002	Phase: III
Study Description: A phase 3, multicenter, randomized, stratified, placebo-controlled, double-blind, parallel group study to investigate the efficacy and safety of ATL-962 in obese patients with type 2 diabetes and dyslipidemia. Code and name of primary active drug group : 399 (agents affecting metabolism n.e.c.), administration : Two ATL-962 60mg tablets will be orally administered three times daily immediately after meal, target : 210 subjects endpoint : Body weight change at the completion of treatment from baseline, planned study duration : 2008-9~2010-7	
Study Design: Multicenter, stratified, randomized, double-blind, parallel-group study	
Study type: Interventional (drug)	
Study Status: On-going	
Condition or disease: Obesity	
Key Criteria for inclusion and exclusion: Key Criteria for inclusion: The subject whose BMI is not less than 25 at the start and the end of the run-in period. The subject whose visceral fat area is not less than 100 cm ² at 8 weeks after the start of the run-in period(-4 Week). The subject who is diagnosed as type 2 diabetes mellitus and the HbA1C values are \geq 6.5% and $<$ 10.0% at the start of the run-in period. The subject who diagnosed as dyslipidemia and meet one of the following criteria for the fasting plasma lipid profile at the start of the run-in period: Hyper-LDL cholesterolemia:LDL cholesterol \geq 140 mg/dL Hypo-HDL cholesterolemia:HDL cholesterol $<$ 40 mg/dL Hypertriglyceridemia:Triglyceride \geq 150 mg/dL Age : 20years old or more Gender : Both Key Criteria for exclusion: The subject who have received any anti-obesity drugs (Mazindol and/or prescribed herb medicines which are indicated as an anti-obesity drug) within 4 weeks prior to the start of the run-in period	
Location of the study sites: Japan (Multicenters)	