

PROTOCOL SUMMARY

Name of Sponsor Company: Takeda Pharma GmbH	Drug Under Study: Pioglitazone Glimepiride
Collaborators: -	
Brief Title of Protocol: Effects of Pioglitazone in Combination with Glimepiride in Comparison to Glimepiride Monotherapy on Metabolic Control in Patients with Type 2 Diabetes mellitus	
Protocol Number: ATS K020	Phase: IIIb
Interventions: Study Drug Intervention Type: Drug Intervention Name: Pioglitazone, Glimepiride	
Study Description: This study should contribute to an increasing understanding of the differential therapy in diabetes by increasing the information on the specific effects of a combination of both drugs on metabolic parameters in patients suffering from diabetes mellitus type 2. <ol style="list-style-type: none"> Pioglitazone + Glimepiride (30/2, 30/4, 45/4 mg) Glimepiride alone (4, 5, 6 mg) 	
Study Type: Multicentre, double-blind, comparative, randomized and parallel two arm study	
Study Status: ongoing	
Study Purpose: To evaluate effects of Pioglitazone in combination with Glimepiride in comparison to Glimepiride alone on metabolic control in type 2 diabetic patients.	
Condition or Disease: Diabetes mellitus type 2	
Key Criteria for Inclusion: <ul style="list-style-type: none"> Type 2 Diabetes according to the ADA Criteria Treatment with Glimepiride monotherapy (1-3 mg per day) 3 months before entering the study Age 30-75 years HbA1c > 6.5%, but < 8.5% and/ or FPG > 7 mmol/l within the last 4 weeks 	
Key Criteria for Exclusion: <ul style="list-style-type: none"> Type 1 Diabetes mellitus Patient < 18 years Anamnesis: History of hypersensitivity to the study drugs or to drugs with similar chemical structures History of severe or multiple allergies Treatment with any other investigational drug within 3 months before trial entry. Progressive fatal disease History of drug or alcohol abuse A history of significant cardiovascular (> NYHA stage II - IV), respiratory, gastrointestinal, hepatic (ALAT > 2.5 times the normal reference range), renal (creatinine > 1.2 mg/dl), neurological, psychiatric and/or hematological disease Blood donation within the last 30 days Pregnancy or breast feeding Sexually active woman of childbearing age not practicing birth control by using contraceptive medication, condoms or intrauterine devices (IUD). Lack of compliance or other similar reason, that, the investigator believes, precludes satisfactory participation in the study Pretreatment with anti diabetic therapy other than Glimepirid 1-3 mg within the last 3 months 	