

PROTOCOL SUMMARY

Name of Sponsor Company: Takeda Pharma GmbH	Drug Under Study: Pioglitazone Metformin Glimepiride
Collaborators:	
Brief Title of Protocol: Effects of a Pioglitazone/Metformin Fixed Combination in Comparison to Metformin in Combination with Glimepiride on Diabetic Dyslipidemia	
Protocol Number: ATS K024 (D-Pio-114)	Phase: IIIb
Interventions: Study Drug Intervention Type: Drug Intervention Name: Pioglitazone, Metformin, Glimepiride	
Study Description: This study is designed to show the superiority of Competact (Pioglitazone/ Metformin) compared with a combination therapy of Glimepiride and Metformin in the context of diabetic dyslipidemia. Involving important general practitioners and diabetologists, this study is planned to support the launch of Competact in Germany: <ol style="list-style-type: none"> 1. Pioglitazone/ Metformin (15 mg/ 850 mg, 2x daily) 2. Glimepiride + Metformin (1mg/850 mg, 2x daily) 	
Study Type: Multicentre, double-blind, randomized and parallel two arm study	
Study Status: ongoing	
Study Purpose: To evaluate the effects of a Pioglitazone/ Metformin fixed combination in comparison to Metformin in combination with Glimepiride 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"> • Metformin treatment (850-2000 mg) as monotherapy within the last 12 weeks • HbA1c > 6,5% • Diabetic dyslipidemia defined as HDL cholesterol \leq 40 mg/dl (1,03 mmol/l) and/or triglyceride levels \geq 150 mg/dl (1,7 mmol/l) • Stable statin treatment is allowed as LDL lowering therapy with no further dose increase while the patient is taking part in the study • Anticoagulation therapy with acetylsalicylic acid and Clopidogrel will be accepted with no further dose increase while the patient is taking part in the study 	
Key Criteria for Exclusion: <ul style="list-style-type: none"> • Anamnestic history of hypersensitivity to the study drugs or to drugs with similar chemical structures • Insulin treated diabetes • Patient <18 or >75 years • History of severe or multiple allergies • Treatment with other OAD in addition to Metformin • Have had more than one unexplained episode of severe • Hypoglycaemia (defined as requiring assistance of another person due to disabling hypoglycaemia) within 6 months prior to entering the study • Fibrate treatment • Gemfibrozil treatment • Niacin treatment • Anticoagulation therapy using heparin, heparin-like drugs, Coumadin, Phenprocoumon, Hirudin, 	

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Protein C, Fondaparinux, Antithrombin III

- 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