

**VILDAGLIPTIN EFFICACY IN COMBINATION WITH METFORMIN FOR EARLY TREATMENT OF T2DM (VERIFY):  
BASELINE CHARACTERISTICS OF ENROLLED PARTICIPANTS FROM ITALY**

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**Aim:** The ongoing VERIFY trial is the first study that aimed to determine the durability of glycaemic control with an early combination of vildagliptin and metformin versus metformin monotherapy in drug-naïve people with diabetes mellitus (T2DM). Here we report the baseline characteristics of the subjects enrolled in the ongoing VERIFY study in Italy. **Methods:** We randomised 45 participants among the global (n=2001) multi-ethnic population, aged 18–70 years, having glycated haemoglobin (HbA1c) levels 48–58 mmol/mol (6.5–7.5%) and body mass index (BMI) 22–40 kg/m<sup>2</sup>. Baseline data included HbA1c, fasting plasma glucose (FPG) and homeostasis model  $\beta$ -cell and insulin assessments for all, globally. Standardised meal-tests, insulin secretion rate relative to glucose (ISR/G), and oral glucose insulin sensitivity (OGIS) were assessed on the global level only. **Results:** Data were collected from the 45 eligible participants (37.8% women). The median disease duration was 3.0 (0.3-22.5) months; mean ( $\pm$ SD) age 58.8 $\pm$ 9.4 years; weight 83.9 $\pm$ 15.0 kg, and BMI 29.7 $\pm$ 4.3; 26.7% of participants were smokers. Baseline HbA1c was 6.9 $\pm$ 0.3 % and FPG was 7.6 $\pm$ 1.2 mmol/L. The global HOMA-% $\beta$  and %sensitivity values were 84% (60-116) and 46% (31-68), respectively. In those undertaking meal-tests, the global mean ISR/G was 28 $\pm$ 12 pmol/min/m<sup>2</sup>/mmol/L and OGIS 353 $\pm$ 57mL/min/m<sup>2</sup>. **Conclusions:** Our current newly diagnosed VERIFY population reflects the characteristic presence of early insulin resistance in subjects with increased demand for insulin associated with obesity. The VERIFY study will provide unique evidence in characterising therapeutic intervention in a global, multi-ethnic, drug-naïve population with hyperglycaemia, focusing on durability of early glycaemic control.

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