Tables

Table 1 Exclusion criteria for the VISION study

- Pregnant or lactating women
- Medical history of type 1 diabetes mellitus or diabetes caused by pancreatic injury
- Secondary diabetes: Cushing syndrome or acromegaly
- Acute complications of diabetes: ketoacidosis or non-ketotic hyperosmolar coma within the past 3 months
- Acute infections within 4 weeks prior to the screening (visit 1) that may affect the efficacy and safety of the study
- Any obvious diabetic complications such as symptomatic autonomic neuropathy, gastroparesis, worsening hyperglycemia in the absence of any comorbid illnesses, and conditions that may affect blood glucose
- History of kidney disease or clinical diagnosis of renal insufficiency indicated by serum creatinine ≥132 μmol/L (≥1.5 mg/dL) in males, and ≥123 μmol/L (≥1.4 mg/dL) in females
- History of a liver disease such as cirrhosis, hepatitis B, or hepatitis C (except carriers)
- Alanine transaminase (ALT), aspartate aminotransferase (AST) greater than 2 times the ULN
- Total bilirubin greater than 2 times the ULN
- History of acute and chronic pancreatitis; malignant tumor in the past 5 years, including leukemia and lymphoma (except for carcinoma in situ of the skin)
- Torsades de pointes ventricular tachycardia
- Persistent, clinically relevant ventricular tachycardia or ventricular fibrillation
- Second-degree atrioventricular block (Mobitz type I and II) or third-degree atrioventricular block, or QTc prolongation (>500 ms)
- Myocardial infarction, coronary artery bypass surgery or percutaneous coronary intervention, unstable angina, or stroke within the past 6 months
- Congestive heart failure requiring medical treatment
- Fasting plasma glucose >15 mmol/L (>270 mg/dL)
- Clinically significant thyroid-stimulating hormone levels outside the normal range at visit 1
- Use of concomitant medications:
  - Other antihyperglycemic agents besides metformin within 12 weeks of visit 1
  - Long-term glucocorticoids (>7 consecutive days of treatment) within 4 weeks of visit 1
  - Treatment with growth hormone or similar drugs
  - Treatment with class Ia, Ib, or Ic, or class III antiarrhythmics
- Treatment with any drug with known and frequent toxicity to a major organ system within the past 3 months
- History of active substance abuse (including alcohol) within the past 2 years
- Use of other investigational drugs at visit 1, or within 30 days or 5 half-lives of visit 1, whichever is longer
- Potentially unreliable patients
- Patients who, in the opinion of the investigator, are unsuitable for the study

ULN: upper limit of normal.