Table 2 Primary, secondary, and exploratory objectives of the VISION study

**Primary objective:**

- To demonstrate that the change from baseline in HbA1c levels after 24 weeks of treatment with vildagliptin 50 mg bid as add-on therapy to metformin 500 mg bid is non-inferior to high-dose metformin

**Secondary objectives:**

- To demonstrate in predefined patient subgroups [based on body mass index (BMI <24 and ≥24 kg/m²) and age (<60 and ≥60 years)] that vildagliptin add-on therapy to metformin is non-inferior to high-dose metformin in the change from baseline in HbA1c levels
- To determine the percentages of patients achieving the target HbA1c level of ≤6.5% in the two treatment arms of the overall population and in the predefined subgroups
- To determine the percentages of patients achieving the target HbA1c level of ≤6.5% without adverse gastrointestinal events in the two treatment arms of the overall population and in the predefined subgroups
- To determine the mean change from baseline to 24 weeks in fasting plasma glucose in the overall population and in the predefined subgroups
- To determine the mean change from baseline to 24 weeks in 2-hour postprandial glucose in a subsample of 464 patients with type 2 diabetes mellitus
- Safety analysis

**Exploratory objectives:**

- To determine the mean change from baseline to 24 weeks in body weight and lipid parameters in the overall population and in the predefined subgroups
- To determine the change from baseline to 24 weeks in β-cell function in a subsample of 464 patients with type 2 diabetes mellitus

BMI: body mass index; HbA1c: glycated hemoglobin.