- The Effectiveness of Diabetes control with vildaGliptin and vildagliptin/mEtformin (EDGE) study compared effectiveness and safety of vildagliptin and other oral anti-diabetic drugs (OAD) in 45868 patients worldwide with inadequately controlled type 2 diabetes mellitus (T2DM) by monotherapy under real-life conditions.
- 754 suitable diabetes patients inadequately controlled with current monotherapy were enrolled in Bulgaria, 384 in the vildagliptin cohort and 369 in the comparator cohort.
- A significant reduction in baseline glycated hemoglobin (HbA1c), statistically greater in the vildagliptin group (1.35%) versus the comparator group (0.55%) was observed after 12 months of treatment.
- More patients in the vildagliptin group achieved the secondary composite endpoint about reduction in HbA1c ≤ 7%, without hypoglycemic event and weight gain ≥3%, compared to the reference group 32.3% and 8.4%, respectively.
- The proportion of subjects successfully achieved the primary endpoint - HbA1c reduction > 0.3%, without any predefined tolerability issues - peripheral edema, confirmed hypoglycemia, interruption due to gastrointestinal reactions, and significant weight gain >5% were significantly more (72.9%) in the vildagliptin group versus (40.1%) in the comparator group ($P < 0.001$) – unadjusted Odds Ratio 4.02 [95% CI 2.96-5.46]
- In the vildagliptin group, the incidence of adverse events (AEs) was 13 (3.4%) versus 7 (1.9%) in the comparator group. The serious AEs reported were 9 (2.3%) and 4 (1.1%) in the vildagliptin and comparator groups, respectively.

This summary slide represents the opinions of the authors. Sponsorship for this study was funded by Novartis Pharma AG. For a full list of acknowledgments and conflicts of interest for all authors of this article, please see the full text online.