- This 12-week randomized study compared the efficacy and safety of vildagliptin 50 mg bid with placebo in Japanese patients with T2DM inadequately controlled (HbA$_{1c}$, 7.0–10.0%) on a stable dose of metformin (250 mg bid or 500 mg bid).

- Stratified randomization was performed to include metformin dose in 1:1 ratio in both the treatment groups.

- Vildagliptin as add-on to metformin showed significant reductions in HbA$_{1c}$ (–1.0%) and FPG (–1.6 mmol/L) vs. placebo ($P<0.001$). Vildagliptin showed a similar reduction in HbA$_{1c}$ (–1.1%) for both the subpopulations (metformin 250 mg or 500 mg bid). Approximately, one-third and two-thirds of vildagliptin-treated patients achieved predefined HbA$_{1c}$ targets of ≤6.5% and <7.0%, respectively.

- Patients in the vildagliptin and placebo groups reported comparable incidences of adverse events (44.1% vs. 41.4%), and no deaths or hypoglycemic events were reported.

- Vildagliptin 50 mg twice daily added to metformin is effective without any tolerability issues in Japanese patients with T2DM.