

Table 1: Adverse events reported by >4% of patients in the safety population

	Vildagliptin 50 mg daily (n = 177)	Vildagliptin 100 mg daily (n = 183)	Placebo (n = 181)
Any AE	112 (63.3)	119 (65.0)	115 (63.5)
Any gastrointestinal AE	17 (9.6)*	27 (14.8)	33 (18.2)
Upper respiratory tract infection	13 (7.3)	14 (7.7)	16 (8.8)
Dizziness	7 (4.0)	11 (6.0)	7 (3.9)
Nasopharyngitis	20 (11.3)	11 (6.0)	13 (7.2)
Influenza	6 (3.4)	10 (5.5)	11 (6.1)
Diarrhea	2 (1.1)	8 (4.4)	10 (5.5)
Nausea	5 (2.8)	8 (4.4)	9 (5.0)
Pain in extremity	2 (1.1)	8 (4.4)	6 (3.3)
Headache	11 (6.2)	7 (3.8)	6 (3.3)

* $P < .05$ vs placebo

Table 2: Efficacy of other oral agents or exenatide added to metformin

<u>Treatment added to metformin</u>	<u>Duration of Treatment</u>	<u>Baseline HbA_{1c}</u>	<u>Mean change or *placebo-subtracted mean change</u>	<u>Reference</u>
<u>Rosiglitazone 4 mg</u>	<u>26 weeks</u>	<u>8.9%</u>	<u>-1.0%*</u>	<u>(1)</u>
<u>Rosiglitazone 8 mg</u>	<u>26 weeks</u>	<u>8.9%</u>	<u>-1.2%*</u>	<u>(1)</u>
<u>Exenatide 5 µg</u>	<u>30 weeks</u>	<u>8.3%</u>	<u>-0.5%*</u>	<u>(2)</u>
<u>Exenatide 10 µg</u>	<u>30 weeks</u>	<u>8.2%</u>	<u>-0.9%*</u>	<u>(2)</u>
<u>Glimepiride titrated to 8 mg</u>	<u>26 weeks</u>	<u>8.4%</u>	<u>-1.3%</u>	<u>(3)</u>
<u>Pioglitazone titrated to 45 mg</u>	<u>26 weeks</u>	<u>8.3%</u>	<u>-1.2%</u>	<u>(3)</u>
<u>Glibenclamide 5 mg</u>	<u>24 weeks</u>	<u>8.5%</u>	<u>-1.5%</u>	<u>(4)</u>
<u>Rosiglitazone 4 mg</u>	<u>24 weeks</u>	<u>8.4%</u>	<u>-1.1%</u>	<u>(4)</u>
<u>Glimepiride 2 mg</u>	<u>1 year</u>	<u>7.9%</u>	<u>-0.9%</u>	<u>(5)</u>
<u>Rosiglitazone 4 mg</u>	<u>1 year</u>	<u>8.0%</u>	<u>-1.2%</u>	<u>(5)</u>
<u>Pioglitazone titrated to 45 mg</u>	<u>2 years</u>	<u>8.7%</u>	<u>-1.0% at 1 year, -0.9% at 2 years</u>	<u>(6)</u>
<u>Gliclazide titrated to 320 mg</u>	<u>2 years</u>	<u>8.5%</u>	<u>-1.0% at 1 year, -0.8% at 2 years</u>	<u>(6)</u>

FIGURE LEGENDS

Figure 1: Patient flow.

Figure 2: Number of patients experiencing specified changes from baseline to endpoint in HbA_{1c}.

Figure 3: Plasma glucose (Panels A and B) and insulin (Panels C and D) before (Baseline, Panels A and C) and after (Endpoint, Panels B and D) 24-week treatment with vildagliptin 50 mg daily (open triangles), vildagliptin 100 mg daily (closed triangles) or placebo (open circles) in patients with T2DM continuing a stable metformin dose regimen. Patients from the primary ITT population who participated in meal tests (n = 54 to 58 patients per treatment group).

Figure 4: Adjusted mean change from baseline to endpoint in fasting lipid parameters (Panel A) or body weight (BW, Panel B) after 24-week treatment with vildagliptin 50 mg daily (shaded bars), vildagliptin 100 mg daily (black bars) or placebo (white bars) in patients with T2DM continuing a stable metformin dose regimen. Primary ITT population, n = 130 to 143 patients per treatment group. * $P < .05$, *** $P < .001$