

Presentation 237-OR / 237 Improved Glycemic Control and Weight Loss with Once-Weekly Dulaglutide vs. Placebo, Both Added to Titrated Daily Insulin Glargine, in Type 2 Diabetes Patients (AWARD-9)

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Abstract:

This double-blind, 28-week (wk) study compared once weekly GLP-1 receptor agonist dulaglutide (DU) 1.5 mg and placebo when added to titrated once daily insulin glargine (\pm metformin), in type 2 diabetes patients (pt) with inadequate glycemic control ($A1c \geq 7\%$ and $\leq 10.5\%$). Patients ($N = 300$; mean baseline [BL] characteristics: age 60.4 y; $A1c$ 8.4%; BMI 32.7 kg/m²; glargine dose 39 U [0.42 U/kg]) were randomized (1:1) to DU 1.5 mg, or placebo; glargine was titrated to fasting plasma glucose target (71 to 99 mg/dL); primary objective was $A1c$ change from BL at wk 28 tested for superiority.

At wk 28 (Table), DU 1.5 mg resulted in significantly greater reductions than placebo in $A1c$ and FSG ($P < 0.001$, both). Body weight decreased with DU 1.5 mg and increased with placebo ($P < 0.001$); hypoglycemia rate (≤ 70 mg/dL and/or symptoms) was 7.69 and 8.56 events/pt/y for DU 1.5 mg and placebo, respectively ($P = 0.488$); severe hypoglycemia events were (n): DU 1.5 mg (1), placebo (0). A statistically greater increase ($P < 0.001$) in glargine dose was observed with placebo compared to DU 1.5 mg. Nausea and diarrhea were more common with DU 1.5 mg (12.0%, 11.3%) vs. placebo (1.3%, 4.0%).

Once weekly DU 1.5 mg compared to placebo, both add-on to titrated daily glargine, resulted in better glycemic control and weight loss without significantly increasing the risk of hypoglycemia.

	DU 1.5 mg (N=150)	Placebo (N=150)	Treatment Difference (SE) ^a
Primary Endpoint (28 wk, ITT)			
$A1c$ change (%), LS Mean (SE)	-1.44 (0.09) [#]	-0.67 (0.09)	-0.77 (0.10)
% of pt with $A1c < 7\%$	66.7 [#]	33.3	--
FSG change (mg/dL), LS Mean (SE)	-44.63 (4.16) [#]	-27.90 (4.08)	-16.73 (4.72)
Weight change (kg), LS Mean (SE)	-1.91 (0.30) [#]	0.50 (0.30)	-2.41 (0.39)
Glargine dose change (U), LS Mean (SE)	12.75 (2.27) [#]	25.94 (2.30)	-13.19 (3.21)
^a Least squares mean difference for DU 1.5 mg vs placebo			
Abbreviations: DU = dulaglutide; FSG = fasting serum glucose; ITT = intent-to-treat; LS = least squares; pt = patient			
[#] 2-sided $P < 0.001$ vs placebo			