EFFICACY AND SAFETY OF LINAGLIPTIN IN HISPANIC/LATINO PATIENTS WITH TYPE 2 DIABETES: POOLED ANALYSIS FROM SIX RANDOMIZED PHASE 3 TRIALS

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Objective: The number of individuals diagnosed with type 2 diabetes is expected to rise disproportionately in Hispanic/Latino populations. We therefore aimed to assess the efficacy and safety of the dipeptidyl peptidase-4 inhibitor linagliptin specifically in Hispanic/Latino patients with type 2 diabetes.

Research Design and Methods: Data from 745 patients who self-identified their ethnicity as Hispanic or Latino were pooled from six randomized placebo-controlled, phase 3 trials. Participants received linagliptin (5 mg/day) or placebo as monotherapy, or in combination with other oral antidiabetes drugs for 18 or 24 weeks.

Results: The placebo-adjusted mean change (95% confidence interval [CI]) in HbA1c from baseline (mean 8.2%) was –0.63% (–0.77, –0.48; P<0.0001) at week 18, and –0.58% (–0.74, –0.42; P<0.0001) at week 24. The placebo-adjusted mean change (95% CI) in FPG from baseline was –11.7 (–19.3, –4.0; P=0.0028) at week 18 and –14.1 mg/dL (–22.0, –6.3; P=0.0004) at week 24. Hypoglycemia incidence was 17.4% with linagliptin and 21.0% with placebo. In patients not receiving concomitant sulfonylurea, the hypoglycemia incidence was 10.1% with linagliptin and 19.4% with placebo. The overall incidence of adverse events (AEs), drug-related AEs, and serious AEs with linagliptin was similar to placebo (AEs 67.6% vs. 68.9%; drug-related AEs 15.1% vs. 18.7%; serious AEs 3.6% vs. 3.0%). Mean body weight remained unchanged in both groups.

Conclusions: In Hispanic/Latino patients with inadequately controlled type 2 diabetes, linagliptin provided clinically meaningful improvements in glycemic control without weight gain or increased risk of hypoglycemia.

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