to -2.16 kg in the overall population. No interaction of weight reduction with age, gender, baseline HbA1c, BMI, eGFR, or duration of T2DM was detected. Treatment by subgroup interactions were detected for geographic region (P=0.03), race (P=0.06), and ethnicity (P=0.09).

Discussion: North Americans had numerically greater weight loss compared with patients from Latin America, Europe, and the Asia/Pacific region. Asians, blacks, and whites tended to have greater weight loss with DAPA than those classified as other; however, there were small numbers of blacks and other patients within each treatment group. Non-Hispanic patients tended to have greater weight loss than Hispanic patients.

Conclusion: Overall, DAPA treatment reduces body weight in patients with T2DM, and this effect appears to be independent of age, gender, baseline HbA1c, BMI, eGFR, and duration of diabetes.

Abstract #206

RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, 24-WEEK STUDY OF LINAGLIPTIN 5 MG/DAY IN BLACK/AFRICAN AMERICAN PATIENTS WITH TYPE 2 DIABETES.

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Objective: Black/African Americans have high rates of type 2 diabetes mellitus (T2DM) yet are under-represented in clinical trials of oral antidiabetic drugs (OADs). Therefore, a trial of the recently developed OAD, linagliptin, was undertaken to specifically recruit African American or black patients with T2DM.

Methods: In this US, multicenter, randomized, placebo-controlled, double-blind trial (NCT01194830), T2DM patients who were treatment-naïve or on ≤1 OAD, and who reported their race as black or African American were randomized to 24 weeks linagliptin 5 mg/day or placebo.

Results: Of 592 patients screened and enrolled, 226 were randomized and received ≥1 dose of study drug (safety set: 106 linagliptin; 120 placebo) and 211 had a baseline and ≥1 on-treatment measurement (efficacy set: 100 linagliptin; 111 placebo). Linagliptin and placebo groups were well balanced for baseline characteristics: overall, 54% were men, mean age was 54 (SD 9.9) years, mean BMI 32.7 (SD 5.7) kg/m², and 72% had hypertension. Across groups, most patients were on metformin or a sulfonylurea, which was continued unchanged; 12% were treatment-naïve. By 24 weeks, mean (SE) HbA1c changes were −0.84 (0.2)% with linagliptin and −0.25 (0.2)% with placebo (placebo-adjusted mean change, P=0.0005) and more patients in the linagliptin group achieved HbA1c <7.0% (26.0% vs 9.0%, OR 4.0, P=0.001) or an HbA1c reduction ≥0.5% (53.0% vs 29.7%, OR 2.8, P=0.0004). Both groups showed weight loss: mean (SD) with linagliptin -1.1 (3.8) kg, placebo -1.1 (7.6) kg. During the 24-week treatment period, 8/100 patients in the linagliptin group and 17/111 in the placebo group required rescue therapy (OR 0.5, P=0.13); AEs were reported in 62/106 (58.5%) and 74/120 (61.7%) of the 2 groups, respectively, most were mild or moderate and considered unrelated to study drug. Overall, the most common AEs were hyperglycemia (linagliptin 2.8%; placebo 9.2%) and nasopharyngitis (linagliptin 3.8%; placebo 5.0%). Serious AEs were reported in 1 patient in the linagliptin group and 2 in the placebo group. Investigator-defined hypoglycemia was rare (3 patients in the linagliptin group and 1 in the placebo group) and no event required external assistance.

Discussion: In this group of black/African Americans with T2DM, linagliptin 5 mg/day was associated with significant improvements in measures of hyperglycemia, and was well tolerated with an AE profile similar to placebo.

Conclusion: This study confirms linagliptin is an efficacious treatment option in black/African American patients with T2DM.

Abstract #207

200 U/ML INSULIN DEGLUDEC IMPROVES GLYCEMIC CONTROL SIMILAR TO INSULIN GLARGINE WITH A LOW RISK OF HYPOGLYCEMIA IN INSULIN-NAÏVE PEOPLE WITH TYPE 2 DIABETES

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Objective: Insulin degludec (IDeg) is a new basal insulin that forms soluble multihexamers that dissociate slowly and steadily upon subcutaneous injection to produce an ultra-long and stable profile with a half-life >24 hours. The 200 U/mL formulation of IDeg (IDeg U200) contains equal units of insulin in half the volume compared to the 100 U/mL formulation, and thus allows larger insulin doses to be administered in a single injection (up to 160 U) with a prefilled pen device. This 26-week, open-label, treat-to-target trial compared the efficacy and safety of once-daily IDeg U200 with 100 U/mL of insulin glargine (IGlar), both in combination with oral antidiabetic drugs.

Methods: Insulin-naïve patients (≥18 years old) with type 2 diabetes (T2D) and HbA1c 7-10% ≥6 months (n=457; mean: 57.5 yrs old, diabetes duration 8.2 yrs, BMI 32.4 kg/m², HbA1c 8.60 (0.1)% and 8.68 (0.1)% for the linagliptin and placebo groups. Across groups, most patients were on metformin or a sulfonylurea, which was continued unchanged; 12% were treatment-naïve. By 24 weeks, mean (SE) HbA1c changes were −0.84 (0.2)% with linagliptin and −0.25 (0.2)% with placebo (placebo-adjusted mean change, P=0.0005) and more patients in the linagliptin group achieved HbA1c <7.0% (26.0% vs 9.0%, OR 4.0, P=0.001) or an HbA1c reduction ≥0.5% (53.0% vs 29.7%, OR 2.8, P=0.0004). Both groups showed weight loss: mean (SD) with linagliptin -1.1 (3.8) kg, placebo -1.1 (7.6) kg. During the 24-week treatment period, 8/100 patients in the linagliptin group and 17/111 in the placebo group required rescue therapy (OR 0.5, P=0.13); AEs were reported in 62/106 (58.5%) and 74/120 (61.7%) of the 2 groups, respectively, most were mild or moderate and considered unrelated to study drug. Overall, the most common AEs were hyperglycemia (linagliptin 2.8%; placebo 9.2%) and nasopharyngitis (linagliptin 3.8%; placebo 5.0%). Serious AEs were reported in 1 patient in the linagliptin group and 2 in the placebo group. Investigator-defined hypoglycemia was rare (3 patients in the linagliptin group and 1 in the placebo group) and no event required external assistance.

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