TRIPLE THERAPY WITH DAPAGLIFLOZIN ADD-ON TO SAXAGLIPTIN PLUS METFORMIN OVER 52 WEEKS IN PATIENTS WITH TYPE 2 DIABETES

M. Herrera Marmolejo1, C. Mathieu2, J. G. Gonzalez Gonzalez3, D. Li4, L. Hansen4, H. Chen5, R. Garcia-Sanchez5, N. Iqbal5

1Endocrinology, Torre Medica, Mexico
2Endocrinology, Katholieke Universiteit Leuven, Belgium
3Department of Internal Medicine, Universidad Autónoma de Nuevo León, Mexico
4Medical Affairs, Bristol-Myers Squibb, USA
5Medical Affairs, AstraZeneca, USA

We previously reported that dapagliflozin (DAPA) add-on to saxagliptin (SAXA) plus metformin (MET) resulted in greater reductions in A1C, fasting plasma glucose (FPG), and body weight (BW) than placebo (PBO)+SAXA+MET after 24 weeks of treatment in patients with type 2 diabetes (T2D) with inadequate glycemic control on SAXA+MET. Here we report results after 52 weeks of treatment. Patients on stable MET+SAXA 5 mg/d with inadequate glycemic control (mean baseline A1C 8.2%) were randomized to PBO or DAPA 10 mg/d plus open-label SAXA+MET. Adjusted mean changes from baseline to week 52 in A1C (–0.74% vs 0.07%; difference [95% CI] –0.81% [–1.06, –0.55]), FPG (–27 vs 10 mg/dL; –37 mg/dL [–48.2, –25.8]), and BW (–2.1 vs –0.4 kg; –1.8 kg [–2.6, –0.9]) were greater with DAPA vs PBO. More patients achieved A1C 7% at week 52 with DAPA (29.4%) vs PBO (12.6%). Fewer patients were rescued or discontinued for lack of glycemic control with DAPA (21%) vs PBO (48%). The proportion of patients with ≥1AE was similar with DAPA (66%) and PBO (71%), and no new safety signals were identified. Hypoglycemia was infrequent (≤2%), with no major episodes of hypoglycemia. Genital infections occurred more with DAPA (6%) vs PBO (1%), but urinary tract infections were similar between the 2 groups (9% vs 10%). Triple therapy with DAPA add-on to SAXA+MET is a durable, effective, and well-tolerated intervention for the treatment of T2D.