- Maintenance of efficacy over time is important to establish for treatments of chronic, progressive conditions such as type 2 diabetes mellitus (T2DM).
- This 48-week, double-blind, parallel-group, phase III study in Europe and Asia randomized patients with T2DM and an inadequate response to open-label glimepiride 4 mg/day to receive add-on placebo (*n* = 146) or dapagliflozin 2.5 mg (*n* = 154), 5 mg (*n* = 145) or 10 mg (*n* = 151).
- Over 48 weeks, the sodium-glucose co-transporter 2 (SGLT-2) inhibitor, dapagliflozin, improved glycemic control and decreased body weight and blood pressure versus placebo. Glycemic efficacy was maintained from 24 to 48 weeks.
- Therapy was well-tolerated in general over 48 weeks. Hypoglycemic events and events suggestive of genital infections were reported more often in patients receiving dapagliflozin versus placebo (9.7–11.3 vs. 6.8% and 5.2–8.6 vs. 1.4%, respectively).
- This is the longest study to date of an SGLT-2 inhibitor added to sulfonylurea monotherapy; given the common use of sulfonylureas in the management of T2DM in a number of countries, sustained efficacy and long-term tolerability with add-on therapies of complementary mechanisms of action such as dapagliflozin is important to establish.

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