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ASIA EDITION

Sanofi provides update on Zynquista type 2 diabetes program

29 July 2019 | News

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Sanofi has announced topline results from three Phase 3 trials of Zynquista™ (sotagliflozin) in adults living with type 2 diabetes from the InSynchrony clinical program. Given the primary endpoint results of blood sugar control (HbA1c) reduction in the SOTA-CKD3 and SOTA-CKD4 studies, Sanofi provided notice to Lexicon that it is terminating the collaboration to develop, manufacture, and commercialize Zynquista in all ongoing global type 1 and type 2 diabetes programs.

At this time, the ongoing Phase 3 clinical trials will continue and there will be no immediate changes. Sanofi has expressed willingness to work with Lexicon to ensure a smooth transition of the studies. Sanofi remains committed to working and supporting the investigators and patients enrolled in the studies while next steps are discussed with Lexicon.

Topline results of the three studies are as follows:

- In SOTA-MET, Zynquista (400 mg) demonstrated a statistically significant reduction in HbA1c compared to placebo at 26 weeks in patients on metformin.
- In SOTA-CKD3, Zynquista (400 mg) showed a statistically significant reduction in HbA1c in the entire population of patients with moderate (stage 3) chronic kidney disease (CKD) and in the subpopulation of patients with a glomerular filtration rate of 45-<60 mL/min/1.73m2 (stage 3A CKD) compared to placebo at 26 weeks. However, a statistically significant reduction in HbA1c was not achieved in the subpopulation of patients with a glomerular filtration rate of 30-<45 mL/min/1.73m2 (stage 3B CKD).
- In SOTA-CKD4, Zynquista (200 mg and 400 mg) did not demonstrate a statistically significant reduction in HbA1c, compared to placebo at 26 weeks in patients with CKD4.

No imbalances or new safety signals were observed in these studies.