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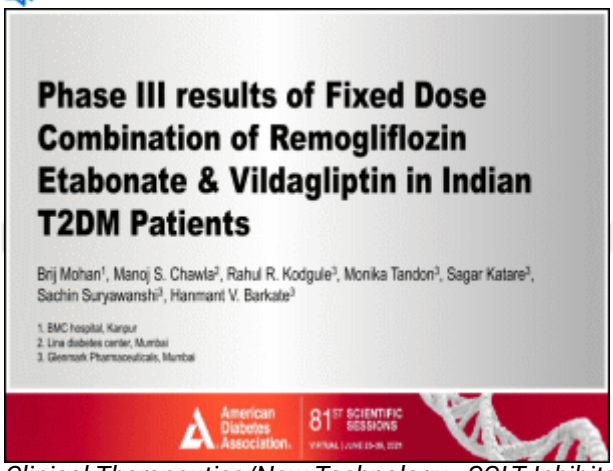
Phase 3 Results of Fixed-Dose Combination of Remogliflozin Etabonate and Vildagliptin in Indian T2DM Patients



Clinical Therapeutics/New Technology - SGLT Inhibitors
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Ask the Author

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Introduction: Remogliflozin Etabonate (RE) and Vildagliptin are approved in India for management of type 2 diabetes mellitus (T2DM), which were evaluated as a fixed dose combination (FDC) in this pivotal phase III study.
Methods: This 16 week, multi-centric, prospective, double blind, double dummy, parallel group, randomized controlled study compared efficacy and safety of FDC of RE 100mg + Vildagliptin 50mg (RV) given twice daily to active comparator of Empagliflozin 25mg + Linagliptin 5mg (EL) given once daily. Adult T2DM patients with HbA1c 8-11% on Metformin stable dose of ≥1500mg for ≥8 weeks before screening were randomized to either of treatment arms. The study endpoints were mean changes from baseline (CFB) in HbA1c (primary), fasting plasma glucose (FPG), post-prandial plasma glucose (PPG), body weight (BW) and blood pressure (BP) for efficacy and adverse events (AE) monitoring for safety assessments.
Results: Of 182 eligible subjects (91 in each arm), 157 (86.3%) subjects completed the study. The baseline demographic characteristics were well balanced between 2 treatment arms. Adjusted mean (SE) change from baseline in HbA1c (%) at week 16 viz. EL arm -1.36 (0.15) vs. RV arm -1.41(0.16); (mITT population; $p<0.001$ in each arm) was comparable between the two treatment arms ($p=0.82$). The mean difference of -0.05% (95%CI: -0.46, 0.36) in HbA1c demonstrated non-inferiority (NI) of RV compared to EL ($p=0.016$ for NI test). Similarly, significant reduction was observed in FPG, PPG, BW and BP which was found to be comparable between the two treatment arms. Drug related AEs were observed in 8.8% and 6.6% subjects of EL and RV arm respectively, with low incidence of hypoglycemia, genital and urinary tract infections (1-3%).
Conclusion: Overall, FDC of Remogliflozin Etabonate + Vildagliptin was found to be efficacious, safe and well tolerated in the treatment of patients with T2DM, and demonstrated non-inferiority to Empagliflozin 25mg + Linagliptin 5mg treatment.

Disclosure: **B.Mohan:** None. **M.S.Chawla:** Speaker's Bureau; Self; Abbott Diabetes, Boehringer Ingelheim Pharmaceuticals, Inc., Colgate-Palmolive, Eli Lilly and Company, Glenmark Pharmaceuticals Limited, Novo Nordisk. **R.R.Kodgule:** Employee; Self; Glenmark Pharmaceuticals Limited. **M.Tandon:** Employee; Self; Glenmark Pharmaceuticals Limited. **S.Katare:** Employee; Self; Glenmark Pharmaceuticals Limited. **S.Suryawanshi:** Employee; Self; Glenmark Pharmaceuticals Limited. **H.V.Barkate:** None.

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