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A Phase III Prospective Active and Placebo- Controlled Randomized Trial of Vilazodone in the Treatment of Major Depressive Disorder

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Statement of the Problem: Depression is a leading cause of psychiatric morbidity in the modern world, and the introduction of selective serotonin reuptake inhibitors (SSRIs) is a revolution in the treatment of depression. Vilazodone, a novel SSRI and 5-HT1A partial agonist, received FDA approval in 2011 to treat the major depressive disorder (MDD) in adults. This study conducted in India aimed to evaluate the efficacy and safety of vilazodone when compared to escitalopram or placebo in patients with MDD.

Methodology: This was a prospective, multicentre, randomized, comparative study of 375 participants over eight weeks of treatment with either vilazodone (10-40mg/day) or escitalopram (10-40 mg/day) or placebo in adult patients with MDD. Primary efficacy was assessed using the Hamilton Rating Scale for Depression (HAM-D-17); secondary efficacy was assessed using the Montgomery-Asberg Depression Rating Scale (MADRS) score and Hamilton Anxiety Scale (HAM-A) score. Safety parameters included adverse events (AEs), clinical laboratory results, vital signs, electrocardiogram (ECG), and Columbia-Suicide Severity Rating Scale (C-SSRS).

Findings: Mean change in the HAM-D-17 total score from baseline to week 8 for vilazodone, escitalopram, and placebo-treated patients in intent-to-treat (ITT) population was: -18.9 (± 7.49), -17.8 (± 6.06), and -7.4 (± 6.32); in ITT population (with Last Observation Carried Forward(LOCF) imputation) was: -17.9 (± 7.71), -17.4 (± 6.19), and -6.4 (± 6.84), and in perprotocol (PP) population was: -19.1 (± 7.20), -17.8 (± 6.08), and -7.7 (± 6.29), respectively. The upper limit of 95% CI (0.56 (ITT); 0.90 (ITT with LOCF Imputation); 0.23 (PP)) of difference in HAM-D-17 between vilazodone 40mg and escitalopram 40mg, which is lower than the defined non-inferiority margin (3.56), proving non-inferiority. The difference between vilazodone 40mg, escitalopram 40mg, and the placebo was statistically significant ($p<0.0001$). No deaths or serious adverse events were reported in this study.

Conclusion & Significance: Vilazodone demonstrated comparable efficacy to escitalopram and superior efficacy over the placebo in the treatment of MDD.

Biography

Dr. Shubhadeep Debabrata Sinha is a Senior Pharmaceutical Physician with over 20 years of experience in Global Clinical Development, Pharmacovigilance, and Medical Affairs in Pharmaceuticals & CROs. He is currently Senior Vice-President and Head- global clinical, medical, and pharmacovigilance operations at Hetero group of pharmaceuticals. He is highly experienced in setting up, expanding, and operating teams in clinical development, global pharmacovigilance, medical affairs in Pharmaceuticals including Dr. Reddy's, Hetero, Glenmark, Organon & CROs including Vimta Labs, Alquest LLC. He has also managed endto-end clinical development of multiple biosimilars including Darbepoetin, Rituximab, Bevacizumab, Adalimumab, and Trastuzumab and a few others at Hetero including domestic and international development & registration.