

Takeda, Lundbeck to present depression study data

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Singapore: Takeda Pharmaceutical and H Lundbeck will be presenting new data from four studies that evaluated effectiveness in treating the overall symptoms of depression in patients taking vortioxetine, an investigational agent under review with the US FDA for the treatment of major depressive disorder (MDD). These data will be presented at the 2013 American Psychiatric Association Annual Meeting (APA) in San Francisco, US.

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The objective of the studies was to evaluate the efficacy and safety profile of vortioxetine in doses ranging from 10-to-20 mg per day, complementing other studies in the New Drug Application (NDA) submission package that included dose ranges of five-to-20 mg per day.

Three of the four pivotal studies met the primary efficacy endpoint as measured by the change from baseline of the Montgomery-Asberg Depression Rating Scale (MADRS) total score at week eight. Statistically significant improvements in overall symptoms of depression were demonstrated, as compared to placebo. A fourth study did not meet the primary endpoint. Results of all four studies provided additional information regarding the safety profile of vortioxetine.

Dr Madhukar Trivedi, professor of psychiatry, UT Southwestern Medical Center, US, who also serves as scientific advisor for Lundbeck and Takeda, said that, "It is important that we continue to seek new options in depression because, even though there are effective treatments available, many patients remain symptomatic. As a clinician, I'm encouraged by these data. They represent an important addition to the broader clinical profile for vortioxetine and support its potential as a new treatment for patients living with MDD."