

FDA to review Takeda's depression drug

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Singapore: Takeda Pharmaceutical and H Lundbeck have received US Food and Drug Administration (FDA) acceptance for a supplemental New Drug Application (sNDA) for review to add clinical data regarding the effect of Brintellix (vortioxetine) on certain aspects of cognitive function in adults with Major Depressive Disorder (MDD).

The FDA is expected to take action on this filing by March 28, 2016.

The cognitive symptoms of depression may go unrecognized by both healthcare providers and patients. Common cognitive complaints include difficulty concentrating, indecisiveness, trouble thinking and forgetfulness.

"Cognitive symptoms are often present in patients suffering from MDD and reducing these symptoms can be challenging," explained Dr John Zajecka, associate professor, Psychiatry, Rush University Medical Center, in Chicago. "Many patients continue to experience certain cognitive and other symptoms even after improvement in their MDD."

"If approved by the FDA, Brintellix would be the first treatment for MDD to include clinical trial data showing an effect on certain aspects of cognitive function in the US label. We look forward to working with the Agency as it considers this important need for patients with MDD," said Mr Charlie Baum, vice president, US Medical Affairs, Takeda.

"The rigorous studies we have conducted with Brintellix evaluating the effects on certain aspects of cognitive functioning in patients with MDD are examples of the commitment our companies have to assessing prevalent cognitive symptoms in patients with MDD - in particular, a core set of symptoms that remain problematic for many people with depression," said Mr Staffan Schuberg, president, Lundbeck US "We look forward to contributing to this emerging area of clinical understanding with the hopes of increasing the awareness of the burden of this disorder."