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NDA for Lundbeck's vortioxetine with US FDA

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NDA for Lundbeck's vortioxetine submitted to US FDA

Singapore: Takeda Pharmaceutical and H. Lundbeck A/S have submitted a new drug application (NDA) to the US Food and Drug Administration (FDA) for the investigational agent vortioxetine (Lu AA21004) for the treatment of major depressive disorder (MDD) in adult patients.

Vortioxetine is under investigation as an antidepressant with multimodal activity that is thought to work through a combination of two complementary mechanisms of actions: receptor activity modulation and reuptake inhibition. The NDA includes data from six short-term placebo controlled studies, including one dedicated study in the elderly, which have been conducted in regions throughout the world and support statistically significant efficacy of vortioxetine in a dose range of five-to-20 mg per day. Efficacy of vortioxetine was also demonstrated in a long-term relapse-prevention study in MDD. The vortioxetine global clinical development program included more than 7,500 individuals exposed to the drug.

In September 2007, Lundbeck and Takeda formed a strategic alliance for the exclusive co-development and co-commercialization in the US and Japan of several compounds in Lundbeck's pipeline for mood and anxiety disorders. The partnership initially focuses on co-development and co-commercialization of the two most advanced compounds in Lundbeck's pipeline for mood and anxiety disorders, vortioxetine and tedatioxetine (Lu AA24530). If approved, the companies plan to co-promote the products in the US and Japan.

MDD, commonly referred to as major depression, is a very common, debilitating illness affecting around 121 million people worldwide, according to the World Health Organization. Results from a landmark, long-term US government study evaluating depression treatment (STAR*D) revealed that only a third of patients with MDD achieve remission at the first stage of treatment. Each additional unsuccessful course of therapy is associated with a progressively lower likelihood of remission and higher relapse rates. Depression was the third leading contributor to the global burden of disease in 2004, and is projected by WHO to be the leading contributor to the worldwide burden of disease by 2030.

"The prevalence and complexity of major depressive disorder remains a growing concern for physicians and those living with

the condition. This NDA submission is a critical milestone for Takeda and our partner Lundbeck, demonstrating our commitment to those living with and treating this condition," said Dr Azmi Nabulsi, president of Takeda Global Research & Development Center. "Together, we are focused on patients' needs and believe that the profile of vortioxetine may translate into therapeutic benefits that help in the treatment of depression."

"We are encouraged by the data results that indicate the potential for vortioxetine, if approved, to help address the needs of people suffering from major depressive disorder who are seeking additional therapeutic options," said Mr Anders Gersel Pedersen, executive vice president and head of Research & Development at Lundbeck. "The vortioxetine NDA represents an important step in the evaluation of a potentially new treatment option for this debilitating disease. We look forward to working with the FDA as they review the data package."