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EMA to review marketing plea for antipsychotic medication

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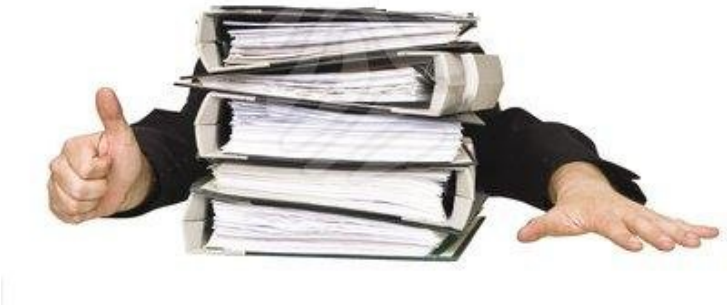
EMA accepts marketing plea for antipsychotic medication by DSP and Takeda



Singapore: The European Medicines Agency (EMA) has accepted the marketing authorization application for review of an atypical antipsychotic medication lurasidone hydrochloride. The product is for the treatment of schizophrenia. The application was filed by Takeda Global Research & Development Centre (Europe), part of Japanese company Takeda Pharmaceutical.

Lurasidone, orally administrated once daily, is an atypical antipsychotic medication discovered and developed by Osaka-headquartered company Dainippon Sumitomo Pharma (DSP) with a unique chemical structure as compared to other existing antipsychotic medicines. Takeda entered into a license agreement with DSP stipulating the joint development and grant of an exclusive commercialization right of the product to Takeda in 26 member states of the European Union (excluding the UK), Switzerland, Norway, Turkey and Russia in March 2011.

The application submission is based on the data from more than 50 clinical trials involving more than 3,800 lurasidone-treated subjects. In phase III clinical trials, in which the efficacy and safety of lurasidone in the treatment of patients with schizophrenia were evaluated, lurasidone demonstrated significantly greater improvement versus placebo in the primary efficacy endpoint. The most commonly observed adverse reactions in patients treated with lurasidone were somnolence, akathisia, nausea and parkinsonism. Clinical trials also demonstrated that lurasidone was well-tolerated with minimal impact on weight or metabolic parameters.

"Lurasidone is the DSP Group's core product for overseas expansion, and I am very pleased that we have achieved the important milestone of submitting an marketing authorization application in Europe," said Masayo Tada, president and chief executive officer of DSP. "Through the cooperation between our two companies, we are aiming for the swiftest approval in order to provide this drug to more patients as soon as possible."

"We are very pleased with the submission of lurasidone in the European Union," said Yasuchika Hasegawa, president & CEO of Takeda. "We believe the submission will lead to the enhancement of our central nervous system franchise, one of our core therapeutic areas. Once approved, we believe we can contribute to the treatment of patients with schizophrenia."