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Otsuka schizophrenia drug seeks EMA nod

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Singapore: Otsuka Pharmaceutical and H Lundbeck's submission of a marketing authorization application (MAA) for the approval of aripiprazole depot formulation has been accepted by the European Medicines Agency (EMA). The application of aripiprazole depot formulation is for the maintenance treatment of adult patients with schizophrenia.

"Our efforts to bring the aripiprazole depot formulation to market demonstrate our long-term commitment to discover, develop and champion treatments for the most challenging psychiatric diseases," said Mr William H Carson, president and CEO, development and commercialization, Otsuka Pharma. "If approved, more patients with schizophrenia will have access to the efficacy and safety profile of aripiprazole in a once-monthly formulation."

"Long-acting therapies are moving to the forefront of treatment for psychiatric disorders, and I am very excited that we now also have submitted this product in Europe," said executive vice president, Mr Anders Gersel Pedersen, who is also head of R&D at Lundbeck. "If approved, aripiprazole depot formulation will offer the clinical propertiespof oral aripiprazole, including its safety and efficacy profile, in a form that is suited to patients who may have difficulties consistently taking their medication."

Aripiprazole depot formulation is the first dopamine D2 partial agonist submitted in Europe as a once-monthly injection. If approved, it will be a new treatment option to address the need for relapse prevention in patients with schizophrenia, a chronic and debilitating disease.

On November 11, 2011, Otsuka and Lundbeck announced an alliance to collaborate on the development and commercialization of up to five early and late stage compounds in development. The two companies will co-commercialise aripiprazole depot formulation in the US and will collaborate on the development and commercialization of aripiprazole depot formulation in other markets worldwide. Aripiprazole depot formulation remains under review by the US FDA.