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Otsuka schizophrenia relapse gets FDA nod

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Singapore: Japan-based Otsuka Pharmaceutical and H Lundbeck have received US FDA approval for Abilify Maintena (aripiprazole) extended-release injectable suspension, an intramuscular (IM) depot formulation indicated for the treatment of schizophrenia.

Abilify Maintena is the first dopamine D2 partial agonist approved as a once- monthly injection. It contributes a new treatment option to address the ongoing need for relapse prevention in patients with schizophrenia, a chronic, debilitating disease.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Abilify Maintena is not approved for the treatment of patients with dementia-related psychosis. Abilify Maintena is contraindicated in patients with a known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Abilify Maintena will be the first commercialized product from the long-term global alliance between Otsuka and Lundbeck to develop CNS medicines worldwide. The companies expect the product will start becoming available in the US on March 18.

"Protection from relapse of schizophrenia is important for patients, their families and the communities in which they live," said study investigator Dr John M Kane, chairman, Psychiatry, The Zucker Hillside Hospital, and VP, Behavioral Health Services, North Shore-LIJ Health System. "As a strong believer in long-acting therapies for schizophrenia, I think it is important for physicians to have a new and effective once-monthly treatment option that can help reduce the risk of relapse and manage symptoms in patients."