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Otsuka, Lundbeck files NDA for schizophrenia drug

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Singapore: Japanese firm Otsuka Pharmaceutical and global firm H Lundbeck have submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for brexpiprazole. This will be for the treatment of schizophrenia and as adjunctive treatment of major depressive disorder (MDD).

The clinical development program for Brexpiprazole included more than 6,500 participants, with more than 5,300 of them receiving brexpiprazole. The NDA is supported by seven completed Phase 2 or 3 clinical studies in the proposed indications. Following the submission the US Food & Drug Administration (FDA) will determine if the NDA is sufficiently complete to allow for a substantive review of the data; a decision from the FDA on initiation of the substantive review is expected in September 2014.

Brexpiprazole is a novel investigational compound discovered by Otsuka and under co-development with Lundbeck. Brexpiprazole is a serotonin-dopamine activity modulator (SDAM) that acts as a partial agonist at 5-HT1A and dopamine D2 receptors at similar potency, and an antagonist at 5-HT2A and noradrenaline alpha1B/2C receptors.