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Lundbeck and Otsuka's brexpiprazole for adult patients with schizophrenia accepted for review by EMA

H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) announce that the European Medicines Agency (EMA) has accepted for review a Marketing Authorization Application for brexpiprazole to treat schizophrenia in adults.

Brexpiprazole is a once-daily, second-generation (atypical) oral antipsychotic that was discovered by Otsuka and co-developed by Otsuka and Lundbeck. The mechanism of action for brexpiprazole in the treatment of schizophrenia is unknown. However, the efficacy of brexpiprazole may be mediated through a combination of partial agonist activity at serotonin 5-HT_{1A} and dopamine D_2 receptors, and antagonist activity at serotonin 5-HT_{2A} receptors. In addition, brexpiprazole exhibits high affinity (subnanomolar) for these receptors as well as for noradrenaline alpha1B/2C receptors.

The application is supported by data from five phase III placebo-controlled clinical trials in adult subjects with schizophrenia including two multinational, six-week, randomized trials and a 52-week randomized maintenance trial.

The EMA is anticipated to complete its review in the second quarter of 2018.

Schizophrenia is a chronic, severe and disabling brain condition. Typically, symptoms are first seen in adults younger than 30 years of age and include hearing voices, believing other people are reading their minds or controlling their thoughts, and being suspicious or withdrawn. In Europe, it is estimated that there are about 5 million people with schizophrenia, with a prevalence of 0.6-0.8%.

Brexpiprazole was approved by the U.S. Food and Drug Administration in July 2015 to treat patients with schizophrenia (as well as an adjunctive treatment of major depressive disorder (MDD)). Brexpiprazole was also approved in February 2017 by Health Canada for the treatment of schizophrenia. In both countries brexpiprazole is distributed and marketed under the brand name REXULTI. If the EMA grants regulatory approval to brexpiprazole, the brand name of the product in the EU would be RXULTI®.