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Otsuka Obtains the Additional Indication of Adjunctive Treatment of Major Depressive Disorder for Rexulti® in Japan

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces that it has obtained approval in Japan for an additional indication for Rexulti® (generic name: brexpiprazole) for the treatment of depression/depressive state. (Administration should be limited to patients who showed an inadequate response to their existing antidepressant therapy.) This is the second indication for this drug in Japan, in addition to schizophrenia.

The phase 3 clinical trial evaluated the efficacy and safety of brexpiprazole as adjunctive therapy in 740 adult patients aged 20 to 64 in Japan, with Major depressive disorder. Brexpiprazole was administered once daily for six weeks, in 1 mg or 2 mg doses, as an adjunctive therapy to SSRI or SNRI antidepressants, for patients who previously had inadequate responses to antidepressant monotherapy. In the study, improvements from baseline on the primary endpoint of the Montgomery-Asberg Depression Rating Scale for patients receiving 1mg and 2mg of brexpiprazole for six weeks as adjunctive therapy were statistically greater than for those receiving adjunctive placebo. Brexpiprazole was generally well tolerated by trial participants, and no new safety concerns were identified.

Rexulti® is expected to become a new treatment option for patients in Japan whose depressive symptoms are not adequately relieved by existing antidepressants. Otsuka will continue to deliver innovative products to meet unmet medical needs around the world.