



September 12, 2022

Company Name	Otsuka Holdings Co., Ltd.
Name of Representative	Tatsuo Higuchi President and Representative Director, CEO
Code Number	4578, Prime market of the Tokyo Stock Exchange
Contact	Yuji Kogure Director, Investor Relations Department (Phone: +81-3-6361-7411)

### **Otsuka Pharmaceutical announces positive results of phase III trial in Japan for brexpiprazole in the treatment of major depressive disorder**

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces positive results from a phase III clinical trial in Japan of brexpiprazole in the treatment of major depressive disorder (ClinicalTrials.gov identifier NCT03697603).

The late-stage trial evaluated the efficacy and safety of brexpiprazole as adjunctive therapy in 740 adult patients in Japan, aged 20 to 64 years, 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.

The trial was a placebo-controlled, randomized, multicenter, double-blind, parallel-group study.

In the study, improvements from baseline on the primary endpoint of the Montgomery-Asberg Depression Rating Scale for patients receiving brexpiprazole as adjunctive therapy were statistically greater than for those receiving adjunctive placebo (2 mg :  $p=0.0312$ , 1 mg :  $p=0.0089$ ).

Secondary endpoints also showed improvement, for adjunctive use of brexpiprazole compared to placebo. Brexpiprazole was generally well tolerated by trial participants, and no new safety concerns were identified. Additional analysis of the trial results is planned to further interpret the efficacy and safety of brexpiprazole.

#### About brexpiprazole

Brexpiprazole was approved in the U.S. in July 2015 as an adjunctive therapy to antidepressants in adults with major depressive disorder and as a treatment in adults with schizophrenia. Brexpiprazole was also approved in 2017 by Health Canada and by the European Medicines Agency in Europe in 2018 for the treatment of schizophrenia. Brexpiprazole has also been approved in multiple other countries. Brexpiprazole is distributed and marketed under the brand name Rexulti®. In Europe, brexpiprazole is distributed and marketed under the brand name Rxulti®.