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Company name	Otsuka Holdings Co., Ltd.
Representative	Tatsuo Higuchi
	President and Representative Director, CEO
Code number	4578 First Section, Tokyo Stock Exchange
Inquiries	Yuji Kogure
	Director, Investors Relations Department

Otsuka Submits New Drug Application in Japan for Brexpiprazole in the Treatment of Schizophrenia

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., today announced the submission of a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare for the manufacture and sale in Japan of brexpiprazole in the treatment of schizophrenia.

Brexpiprazole is a serotonin-dopamine activity modulator (SDAM) that acts as a partial agonist at 5-HT_{1A} and dopamine D_2 receptors, and an antagonist at 5-HT_{2A} and noradrenaline alpha_{1B/2C} receptors.

Brexpiprazole was discovered by Otsuka and is in global co-development with the Danish company Lundbeck. This drug was approved in the U.S. by the Food and Drug Administration in July 2015 for the treatment of schizophrenia and as adjunctive treatment of major depressive disorder (MDD). It was launched there in August 2015 with the brand name "REXULTI[®]".