

Health Canada Approves Otsuka and Lundbeck's REXULTI® (brexpiprazole) as Adjunctive Treatment of Major Depressive Disorder

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MONTREAL, Feb. 22, 2019 /CNW Telbec/ - Otsuka Pharmaceutical Canada Inc. (Otsuka) and Lundbeck Canada Inc. (Lundbeck) announce that Health Canada issued a Notice of Compliance for REXULTI® (brexpiprazole) for use as an adjunct to antidepressants for the treatment of major depressive disorder (MDD) in adult patients with an inadequate response to prior antidepressant treatments during the current episode.

"Brexpiprazole, is a new option for patients with MDD who require augmentation therapy. Its unique mechanism of action and potential benefits will be a new source of optimism for patients suffering from Depression" said Dr. Diane McIntosh.

"The Mood Disorders Society of Canada (MDSC) welcomes Health Canada's recent decision to approve REXULTI® (brexpiprazole) for the adjunct treatment of Major Depressive Disorder (MDD). For many patients suffering from depression who have not been able to achieve remission with standard treatments, the addition of this innovative and novel treatment offers hope for patients and their families. In a recent study, over 4% of Canadians met the criteria for a major depressive episode, and it is crucially important to have new and innovative treatments to address this health crisis. MDSC is engaged on an ongoing basis in a wide range of projects and initiatives designed to support the inclusion of persons with disabling mental illnesses in Canadian society and has taken a lead proactive role in public policy and program development in many capacities on the national stage." said Dave Gallson, National Executive Director at MDSC.

About Major Depressive Disorder

Major depressive disorder (MDD), commonly referred to as major depression, is a chronic and disabling illness characterized by persistent low mood and markedly diminished interest or pleasure in everyday activities. It is estimated by the World Health Organization that MDD affects over 300 million people worldwide ⁽¹⁾. Also, Statistics Canada reported in 2013 that approximately 1.3 million Canadians aged 15 years and older met the criteria for depression in the previous year ⁽²⁾. MDD is the leading cause of disability worldwide and is a major contributor to the overall global burden of disease ⁽¹⁾.

About REXULTI®

REXULTI® (brexpiprazole) was discovered by Otsuka and co-developed by Otsuka and Lundbeck. It is co-marketed by the two companies. REXULTI® was approved by Health Canada for the treatment of schizophrenia in adults in February 2017. REXULTI® is given in a once-daily oral dose that can be taken with or without food. Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. REXULTI® is not approved for the treatment of patients with dementia. REXULTI® is not indicated in pediatric patients and its use is not recommended in this population. REXULTI® is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For more information about REXULTI®, please visit <http://otsukacanada.com> or <https://www.lundbeck.com/ca>.

About Otsuka

Otsuka Canada Pharmaceutical Inc. (OCPI) is an innovative, fast-growing health care company that commercializes Otsuka medicines in Canada. OCPI aims to improve the quality of life and health of patients through its commitments to neuroscience, cardiovascular health, oncology and nephrology. OCPI was established in 2010, with headquarters in Saint-Laurent, Quebec.

OCPI is part of Otsuka Pharmaceutical Co., Ltd., a global healthcare company with the corporate philosophy: "Otsuka – people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

Otsuka Pharmaceutical is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., based in Tokyo, Japan. The Otsuka group of companies employed 47,000 people worldwide and had consolidated sales of approximately CAD 15.4 billion (approximately USD 11.6 billion) in 2018. All Otsuka stories start by taking the road less travelled. Learn more about Otsuka Pharmaceutical Company on its global website at <https://www.otsuka.co.jp/en>. Learn more about Otsuka in Canada at <http://otsukacanada.com>.

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company highly committed to advancing neuroscience, developing new and innovative treatments and supporting patient communities. For this purpose, Lundbeck is engaged in the research, development, manufacturing, marketing and sale of pharmaceuticals across the world. The company's products are targeted at the disease areas within psychiatry and neurology. Lundbeck's employees in more than 50 countries are tirelessly dedicated to restoring brain health, so that every person can be at their best. Lundbeck's products are registered in more than 100 countries, with production facilities in Denmark, France and Italy, and a research center based in Denmark. Lundbeck generated revenue of DKK 18.1 billion in 2018.

A division of Denmark-based H. Lundbeck A/S, Lundbeck Canada Inc. has been a trusted source of innovative new treatments for Canadians since 1995 with headquarters just outside Montreal. As a patient-focused partner in Canadian healthcare, Lundbeck Canada seeks to improve the quality of life for people living with brain diseases.

REXULTI® is a registered trademark of Otsuka Pharmaceutical Co., Ltd., used under license by Otsuka Canada Pharmaceutical Inc.

References

1. World Health Organization Fact sheet on Depression (updated March 2018). <http://www.who.int/mediacentre/factsheets/fs369/en/>, accessed on 13 February 2019
2. Pearson, Caryn, Teresa Janz and Jennifer Ali. 2013. "Mental and substance use disorders in Canada" Health at a Glance. September. Statistics Canada Catalogue no. 82-624-X

SOURCE Otsuka

For further information: For all media inquiries, please contact: Otsuka Canada Pharmaceutical Inc., Allison Rosenthal, General Manager, Allison.rosenthal@otsuka-ca.com; Or, Lundbeck Canada Inc., Sylvie Pilon, Vice-President and General Manager, sypi@lundbeck.com