



GEDEON RICHTER

Established in 1901

Health Canada Approves VRAYLAR® (cariprazine) for the Treatment of Bipolar I Disorder and Schizophrenia in Adults

VRAYLAR® is a new atypical antipsychotic medication with partial agonist activity at central dopamine D₃ receptors in addition to targeted activity at D₂ and serotonin 5-HT_{1A} and 5-HT_{2A} receptors.¹

Budapest, Hungary – 27 April 2022 – Richter's partner, AbbVie (NYSE: ABBV), a global, research and development-based biopharmaceutical company announced today that Health Canada has approved VRAYLAR® (cariprazine) as monotherapy for the acute management of manic, mixed, and depressive episodes associated with bipolar I disorder in adults, as well as the treatment of schizophrenia in adults.¹

Bipolar I disorder is a mental illness characterized by extreme mood swings that can impact an individuals' ability to think, behave and function.² It can consist of three states which includes manic, depressive, and mixed episodes.³ While the causes of bipolar I disorder are unknown, biological factors can play a role and can be difficult to diagnose due to the wide range of symptoms.³

Schizophrenia is a severe mental illness that can also impact a person's ability to function, and often presents symptoms that can change over time. Symptoms can include hallucinations, disorganized speech, social withdrawal, and catatonic behaviour.³

"I have seen firsthand what impact bipolar I disorder and schizophrenia can have on a person's life. These are complex illnesses that can be difficult to treat and manage. It is important that we have additional treatment options available for persons affected," – says Dr. Roger S. McIntyre, M.D., FRCPC, Professor of Psychiatry and Pharmacology, University of Toronto. "As a healthcare professional, I am pleased to hear that this treatment is now available for Canadians who live with bipolar I disorder or schizophrenia."

It's estimated 2.2% of Canadians will experience bipolar I disorder in their lifetime and can impact both men and women equally,⁴ while an estimated 300,000 Canadians are impacted by schizophrenia.³ Stigma remains prevalent in both disorders, with patients often experiencing discrimination and difficulty in accessing resources and treatment.⁵

Chemical Works of Gedeon Richter Plc.

“We know that living with bipolar I disorder can present various challenges impacting the daily lives of patients and their families,” – Dave Gallson, National Executive Director, Mood Disorders Society of Canada. “The Mood Disorders Society of Canada thanks Health Canada for the approval of VRAYLAR[®], which will support those in the community in managing this mental illness. It is encouraging to see new treatment options for people with bipolar I disorder.”

“We are pleased to see the progress in new treatments to support Canadians living with schizophrenia,” – says Chris Summerville, CEO of the Schizophrenia Society of Canada. “Patients are looking for convenient and safe treatments to support their health and recovery. VRAYLAR[®] will offer new hope for many Canadians and help minimize the burdens associated with schizophrenia to support patients and their caregivers.”

“This is another important milestone as cariprazine is becoming a globally available treatment option for patients suffering of bipolar I disorder and schizophrenia,” – says Dr István Greiner, R&D Director of Richter. “We are confident that this novel and convenient therapy will successfully meet the needs of both Canadian patients and healthcare professionals.”

About VRAYLAR[®] (cariprazine)¹

VRAYLAR[®] is an oral, once daily atypical antipsychotic approved as monotherapy for the acute management of manic, mixed, and depressive episodes associated with bipolar I disorder in adults, as well as the treatment of schizophrenia in adults.

The mechanism of action of cariprazine in schizophrenia and bipolar I disorder is unknown. However, the therapeutic effect of cariprazine may be mediated through a combination of partial agonist activity at central dopamine D₃, D₂ and serotonin 5-HT_{1A} receptors and antagonist activity at 5-HT_{2A} receptors. Cariprazine forms two major metabolites, desmethyl cariprazine (DCAR) and didesmethyl cariprazine (DDCAR), that have *in vitro* receptor binding and functional activity profiles similar to the parent drug.

VRAYLAR[®] is contraindicated in patients who are hypersensitive to cariprazine or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. VRAYLAR[®] is also contraindicated with concomitant use with strong and moderate CYP3A4 inhibitors / inducers. Due to the slow elimination of cariprazine and its metabolites, treatment with strong and moderate CYP3A4 inhibitors must be initiated at least 2 weeks after VRAYLAR discontinuation.

VRAYLAR is being developed jointly by AbbVie and Gedeon Richter Plc, with AbbVie responsible for commercialization in the U.S., Canada, Japan, Taiwan and certain Latin American countries (including Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Mexico, Peru and Venezuela).

Please consult the VRAYLAR® Product Monograph at www.allergan.ca.

About Richter

Gedeon Richter Plc. (www.gedeonrichter.com), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China and in Latin America. Having reached a market capitalization of EUR 4.4 billion (USD 5.0 billion) by the end of 2021, Richter's consolidated sales were approximately EUR 1.8 billion (USD 2.1 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's Healthcare field worldwide. Richter is also active in biosimilar product development.

For further information:

Investors:

Katalin Ördög: +36 1 431 5680

Media:

Zsuzsa Beke: +36 1 431 4888

References :

¹ VRAYLAR Product Monograph. Allergan Inc. April 22nd 2022.

² CAMH. Bipolar Disorder. Retrieved from <https://www.camh.ca/en/health-info/mental-illness-and-addiction-index/bipolar-disorder>. Accessed March 2022.

³ Schizophrenia Society of Canada. Learn more about Schizophrenia. Retrieved from <https://schizophrenia.ca/learn-more-about-schizophrenia/>. Accessed March 2022.

⁴ Canadian Psychological Association. "Psychology Works" Fact Sheet: Bipolar Disorder. Retrieved from <https://cpa.ca/psychology-works-fact-sheet-bipolar-disorder/>. Accessed March 2022.

⁵ CAMH. Addressing Stigma. Retrieved from <https://www.camh.ca/en/driving-change/addressing-stigma>. Accessed March 2022.