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PRESS RELEASE

AbbVie's VRAYLAR® (cariprazine) Receives Positive Reimbursement Recommendation by Canada's Drug Agency for the Treatment of Schizophrenia

- *VRAYLAR, an atypical antipsychotic medication, received its Notice of Compliance from Health Canada on April 22, 2022.*
- *Following the positive recommendation from INESSS issued in October 2022, VRAYLAR completed negotiations at pCPA and has an active letter of intent (LOI). Québec and the Federal Plans (NIHB, CSC and VAC) have subsequently listed VRAYLAR, for the treatment of schizophrenia, as a result of this completed negotiation and LOI.*

MONTREAL, QC, September 4, 2024 – AbbVie (NYSE: ABBV) today announced that Canada's Drug Agency (CDA, formerly CADTH) has recommended that VRAYLAR be reimbursed with conditions, for the treatment of schizophrenia in adults.

This recommendation supersedes the CADTH recommendation for this drug and indication dated August 26, 2022.

"We applaud CDA for this positive reimbursement recommendation, along with the acknowledgement of the important unmet need for better management of negatives symptoms of schizophrenia," says Chris Summerville, CEO of the Schizophrenia Society of Canada. "We are hopeful that this step towards equitable access to VRAYLAR will help meet this need for many Canadians."

Schizophrenia is a severe mental illness that can 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. An estimated 300,000 Canadians are impacted by schizophrenia.[1] Only 15% of schizophrenia patients in Canada are employed[2], which means that they likely do not have access to private insurance and rely on public drug plans to access the medications they require to manage their symptoms.

"Psychiatric disorders are complex and challenging to treat because every individual I see has unique needs. In order for me to personalize treatment, due to the differences in treatment response and tolerability, I need access to many options," says psychiatrist, Dr. Diane McIntosh. "I'm really happy with CDA's recommendation regarding cariprazine because it's a unique compound that has become an important tool I can offer to my patients, as we build their path to recovery. This is great news for Canadians living with this severe mental illness."

"This important milestone for VRAYLAR speaks to AbbVie's commitment to not only bring new therapeutic options for severe mental illness to Canada, but to work with governments, clinicians and community stakeholders to reduce disparities and make these medicines accessible to all Canadian patients," says Rami Fayed, Vice President and General Manager, AbbVie Canada.

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[1] Schizophrenia Society of Canada. Learn more about Schizophrenia. https://schizophrenia.ca/about-schizophrenia/ . Accessed August 2024.

[2] Canada's Public Policy Forum (2014). Schizophrenia in Canada: The Social and Economic Case for a Collaborative Model of Care. 2014.: https://ppforum.ca/wp-content/uploads/2018/03/Schizophrenia-in-Canada-Final-report.pdf Accessed August 2024.

About VRAYLAR® (cariprazine)[3]
VRAYLAR is an oral, once daily atypical antipsychotic, is indicated:

- for the treatment of schizophrenia in adults.
- as monotherapy for:
    - bipolar mania: acute management of manic or mixed episodes associated with bipolar I disorder in adults, and
    - bipolar depression: acute management of depressive episodes associated with bipolar I disorder 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-HT1A receptors and antagonist activity at 5-HT2A 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 for important safety information on serious warnings and precautions, other warnings and precautions, adverse reactions, interactions, dosing and conditions of use. The Product Monograph is also available by calling 1-888-704-8271.

About AbbVie
AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on Twitter, on Instagram or find us on LinkedIn.

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[3] VRAYLAR Product Monograph. AbbVie Corporation. https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/VRAYLAR_PM_EN.pdf Accessed August 2024.