



PRESS RELEASE

AbbVie's VYALEV™ (foslevodopa/foscarbidopa solution) Available for the Treatment of Advanced Parkinson's Disease in Canada

- *VYALEV is the first-and-only subcutaneous 24-hour infusion of levodopa-based therapy for the treatment of advanced Parkinson's disease (aPD) in Canada.*
- *Advanced Parkinson's disease patients now have a non-surgical treatment option that addresses an unmet need within this community.*
- *In clinical trials, patients taking VYALEV achieved the primary endpoint of a reduction in motor fluctuations and morning akinesia, as well as improvements in sleep quality and quality of life.^{1,2}*
- *Announcement underscores AbbVie's longstanding commitment to deliver innovative medicines for people living with neurological disorders.*

MONTREAL, QC, February 8, 2024 – AbbVie (NYSE: ABBV), today announced that VYALEV (foslevodopa/foscarbidopa solution) is now available for the treatment of motor fluctuations in patients with advanced levodopa-responsive Parkinson's disease who do not have satisfactory control of severe, debilitating motor fluctuations and hyper- /dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products.³

VYALEV is the first-and-only subcutaneous 24-hour infusion of levodopa-based therapy for the treatment of aPD.

In Canada, Parkinson's disease affects more than 100,000 Canadians aged 40 and older, with approximately 30 people diagnosed with the condition every day.⁴ Within the next 10 years, this number is expected to increase to 163,700 Canadians living with the condition, and 50 new diagnoses per day.^{5,6}

Advanced Parkinson's disease is a progressive and chronic movement disorder characterized by tremor, muscle rigidity, slowness of movement and difficulty with balance resulting from the loss of dopamine-producing brain cells.⁷ The symptoms of the disease are frequently talked about in terms of "on" and "off" time. "On" time is when symptoms are controlled and "off" time is when symptoms return between medication doses.^{8,9}

"As Parkinson's progresses, oral treatment options may no longer control symptoms appropriately. Despite this, only a relatively small number of patients consider device-aided therapy, an option that requires surgery," said Toronto-based neurologist Dr. Alfonso Fasano, M.D., Ph.D., FAAN. "With the availability of subcutaneous foslevodopa/foscarbidopa solution, aPD patients now have a less invasive treatment option that continuously delivers medication, enabling 24-hour symptom control that can help improve quality of life."

"AbbVie is proud to deliver the first new treatment for advanced Parkinson's disease in a decade, bring a much-needed new non-surgical option to patients who seek options when managing their disease," says Rami Fayed, Vice President and General Manager, AbbVie Canada. "This new therapy builds on our remarkable legacy with DUODOPA and is proof of our



longstanding commitment to people living with Parkinson's disease and their care partners in Canada”

When Parkinson's disease is advancing, patients often experience a decrease in their ability to perform daily activities such as getting dressed or making a meal,¹⁰ and are therefore cared for by a family member or care partner.¹¹

“As Parkinson's progresses, there is a high physical and emotional toll not only for the person but also their family and care partners who for some play a critical role in managing their Parkinson's,” said Karen Lee, President and Chief Executive Officer of Parkinson Canada. “No one experiences Parkinson's the same way, which is why it is critical that people with Parkinson's have access to options that will help manage their symptoms across all stages of the disease. This announcement gives hope to people with Parkinson's that they will have access to more options to help manage their disease even in the advanced stages.”

About VYALEV

VYALEV (foslevodopa/foscarbidopa) is a solution of levodopa and carbidopa prodrugs for continuous subcutaneous infusion for the treatment of advanced Parkinson's disease in patients whose motor symptoms are not controlled by oral medications.³

About the Phase 3 M15-741¹ Study

The Health Canada approval of VYALEV was supported by the pivotal Phase 3 M15-741¹ study, a 12-month, single arm, open-label study evaluating the safety, efficacy and tolerability of 24-hour daily exposure of continuous subcutaneous infusion of VYALEV in people with advanced Parkinson's disease whose motor symptoms were inadequately controlled by their current treatment. Findings showed a reduction in motor fluctuations and morning akinesia (“off” time upon awakening), as well as improvements in sleep quality and quality of life through week 52. More information on the study can be found on www.clinicaltrials.gov (NCT04379050).

About the Phase 3 M15-736² Study

The Phase 3 randomized, double-blind, double-dummy, active-controlled study compared the efficacy, safety and tolerability of ABBV-951 (foslevodopa/foscarbidopa solution) to oral LD/CD in advanced PD patients. Approximately 130 adult participants with advanced PD were enrolled in the study across 80 sites worldwide. Findings showed that patients had significant increases in hours of “On” time without troublesome dyskinesia, compared to oral immediate-release carbidopa/levodopa. The treatment duration was 12 weeks. More information on the study can be found on www.clinicaltrials.gov (NCT04380142).

Please consult the VYALEV™ [product monograph here](#).

About AbbVie in Neuroscience

At AbbVie, our commitment to people around the world living with neurological and psychiatric disorders is unwavering. With more than three decades of experience in neuroscience, we are providing meaningful treatment options today and advancing innovation for the future. AbbVie's Neuroscience portfolio consists of approved treatments in neurological conditions, including migraine, movement disorders, and psychiatric disorders, along with a robust pipeline of transformative therapies. We have made a strong investment in research and are committed to



building a deeper understanding of neurological and psychiatric disorders. Every challenge makes us more determined and drives us to discover and deliver advancements for those impacted by these conditions, their care partners, and clinicians. For more information, visit www.abbvie.ca.

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines and solutions 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, and eye care – and products and services in our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on [X Instagram](#), or [LinkedIn](#).

For more information on AbbVie's complete Parkinson's disease portfolio, please visit www.abbvie.ca.

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¹ A Study to Evaluate the Safety and Tolerability of ABBV-951 in Participants With Parkinson's Disease (PD). ClinicalTrials.gov. 2022. Available at: <https://clinicaltrials.gov/ct2/show/NCT03781167>. Accessed February 8, 2023.

² Safety and efficacy of continuous subcutaneous foslevodopa-foscarbidopa in patients with advanced Parkinson's disease: a randomised, double-blind, active-controlled, phase 3 trial. The Lancet Neurology. Available at: [https://www.thelancet.com/journals/lanneur/article/PIIS1474-4422\(22\)00400-8/fulltext](https://www.thelancet.com/journals/lanneur/article/PIIS1474-4422(22)00400-8/fulltext). Accessed February 8, 2023.

³ Product Monograph. 2023. https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/VYALEV_PM_EN.pdf

⁴ "Parkinson's Disease". Parkinson Canada. Available at: <https://www.parkinson.ca/about-parkinsons/>. Accessed: March 16, 2023.

⁵ Public Health Agency of Canada. Canadian Chronic Disease Surveillance System (CCDSS), Data Tool 2000–2016, 2018 Edition. Ottawa (ON): Public Health Agency of Canada; 2019.

⁶ Neurological Health Charities Canada (NHCC), Health Canada, Public Health Agency of Canada (PHAC), Canadian Institute of Health Research (CIHR). MAPPING CONNECTIONS: An Understanding of Neurological Conditions in Canada. Sept. 2014. pg.68.

⁷ About Parkinson's: Parkinson's 101. The Michael J. Fox Foundation for Parkinson's Research. Available at: <https://www.michaeljfox.org/understanding-parkinsons/i-have-got-what.php#q2>

⁸ "Wearing off and motor fluctuations." Available at: <https://www.parkinsonseurope.org/about-parkinsons/symptoms/motor-symptoms/wearing-off-and-motor-fluctuations/>. Accessed February 8, 2023.

⁹ "'Off' Time in Parkinson's Disease." (2022). Available at: <https://www.michaeljfox.org/time-parkinsons-disease>. Accessed March 10, 2023.

¹⁰ K Ray Chaudhuri and Stuart H Isaacson. (2013). Morning Akinesia and the Potential Role of Gastroparesis – Managing Delayed Onset of First Daily Dose or Oral Levodopa in Patients with Parkinson's Disease. Available at: <https://touchneurology.com/movement-disorders/journal-articles/morning-akinesia-and-the-potential-role-of-gastroparesis-managing-delayed-onset-of-first-daily-dose-of-oral-levodopa-in-patients-with-parkinsons-disease/>. Accessed February 8, 2023.

¹¹ Pablo Martinez-Martin et al. Impact of advanced Parkinson's disease on caregivers: an international real-world study. Journal of Neurology. Published January, 2023.