



PRESS RELEASE

Health Canada Approves AbbVie's CONSTELLA® (linaclotide) for the Treatment of Functional Constipation in Pediatric Patients 6 to 17 Years of Age

- *CONSTELLA is the first and only Health Canada-approved prescription therapy for functional constipation in this patient population*
- *Submission is based on positive Phase 3 study data demonstrating linaclotide (72mcg) resulted in increases in frequency of spontaneous bowel movements (SBM) in children and adolescents aged 6 to 17 years*

MONTREAL, QC, September 10, 2024 – AbbVie (NYSE: ABBV), today announced that Health Canada has approved CONSTELLA® (linaclotide) as a once-daily oral treatment for children and adolescents 6 to 17 years of age with functional constipation. CONSTELLA is the first and only Health Canada-approved prescription therapy for functional constipation in this patient population.

Functional constipation is a chronic condition characterized by hard, infrequent bowel movements that are often difficult or painful to pass.¹ Considered the most common functional gastrointestinal disorder in children, functional constipation has a pooled global prevalence of 14.4%.² Core symptoms of functional constipation include decreased stool frequency, harder stool consistency, painful passage of stools, and fecal incontinence.¹

“Constipation is a common issue in childhood that can significantly impact a child's quality of life and cause considerable stress for their families. These children and families will be grateful to have a new prescription treatment option that can offer symptom relief and improve the overall well-being of the child and family, making daily life more manageable,” said Dr. Melanie Schmidt, Division of Paediatric Gastroenterology and Hepatology at Children’s Hospital in London, Ontario. “It's great to see progress in treatment options that address both the symptoms and the broader quality of life issues.”

The approval of CONSTELLA is based on efficacy and safety results from a Phase 3 clinical trial, which met the primary endpoint evaluating linaclotide (72 mcg) for increased frequency of spontaneous bowel movements (SBM) in patients aged 6 to 17 years.³

“Functional constipation is difficult enough when you’re an adult, but for children, the condition can be unbearable. Changing the diet is not always the solution, and medication might be the only relief,” explained Gail Attara, President and Chief Executive Officer of the Gastrointestinal Society. “Constipation can interfere with daily activities and cause chronic pain. Parents will appreciate now having a prescription medication to help their children.”



“Although functional constipation is common among pediatric patients, it has long been difficult to manage because it is often unrecognized and under-treated,” said Rami Fayed, Vice President and General Manager, AbbVie Canada. “This approval marks an important milestone that will make a big difference for children and adolescents, as well as their parents, demonstrating our tireless work to advance standards of care for all Canadians.”

CONSTELLA is also indicated for the treatment of adults with chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C).

About the linaclotide study ³

In the multicenter double-blind Phase 3 study evaluating CONSTELLA in patients 6 to 17 years of age with functional constipation, a total of 328 patients were randomized in a 1:1 ratio between linaclotide or placebo. Linaclotide showed a statistically significant and clinically meaningful improvement compared to placebo in 12-week spontaneous bowel movement (SBM) frequency rate (SBMs/week), the primary endpoint. For patients who cannot swallow a capsule, Constella can be added to water or applesauce. The Phase 3 study demonstrated consistent safety in the pediatric population. The most common adverse event in the pediatric Phase 3 study was diarrhea which occurred in 4% of linaclotide-treated patients versus 2% in the placebo group and only 1 patient dropped out of the study. More information can be found on www.clinicaltrials.gov (NCT04026113).

About CONSTELLA (Linaclotide) ⁴

Linaclotide is a guanylate cyclase-C (GC-C) agonist that binds GC-C locally in the intestine with minimal systemic exposure. Linaclotide has been shown to both accelerate GI transit and reduce intestinal pain. CONSTELLA (linaclotide) is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC) in adults as well as for the treatment of functional constipation in children and adolescents age 6 to 17. AbbVie licensed linaclotide from Ironwood Pharmaceuticals for development and commercialization in Canada. CONSTELLA and its design are trademarks of Ironwood Pharmaceuticals, Inc., used under license by AbbVie Corporation.

For important safety information, please consult the CONSTELLA Product Monograph at www.abbvie.ca.

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 our Allergan Aesthetics portfolio. For more



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¹ Di Lorenzo C, Hyams JS, Saps M, et al. Chapter 16: Childhood functional gastrointestinal disorders: Child/Adolescent. In: Drossman DA, Chang L, Chey WD, et al. Rome IV: Functional Gastrointestinal Disorders: Disorders of Gut-Brain Interaction. Raleigh, NC: Rome Foundation; 2016.

² Tran, DL, Sintusek, P. Functional constipation in children: what physicians should know. [World J Gastroenterol](#). 2023 Feb 28; 29(8): 1261–1288. Available at: [10.3748/wjg.v29.i8.1261](https://doi.org/10.3748/wjg.v29.i8.1261). Accessed August 27, 2024.

³ Di Lorenzo, C, Khlevner, J, Rodriguez-Araujo, G, et al. Efficacy and safety of linaclotide in treating functional constipation in paediatric patients: a randomised, double-blind, placebo-controlled, multicentre, phase 3 trial. *The Lancet. Gastroenterology & Hepatology*, 2024-03, Vol.9 (3), p.238-250. Available at: [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(23\)00398-9/abstract](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(23)00398-9/abstract). Accessed August 27, 2024.

⁴ Constella (linaclotide) Product Monograph. AbbVie Corporation. Available at: https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/CONSTELLA_PM_EN.pdf Accessed on September 10, 2024.