

## PRESS RELEASE

### **AbbVie Receives Health Canada Approval of HUMIRA® (adalimumab) for the Treatment of Pediatric Patients with Moderately to Severely Active Ulcerative Colitis**

- *With this approval, HUMIRA, an anti-TNF monoclonal antibody, offers pediatric patients from five years of age with moderately to severely active ulcerative colitis (UC) the first subcutaneous anti-TNF treatment option<sup>1</sup>*
- *Approval based on results from the pivotal Phase 3 ENVISION I study, the largest clinical trial in pediatric ulcerative colitis to date, showing HUMIRA provided significant rates of response and remission both at week 8 and 52<sup>1,2</sup>*

**MONTREAL, QC, April 22, 2021** – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that Health Canada has approved HUMIRA® (adalimumab) for inducing and maintaining clinical remission in pediatric patients five years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy including corticosteroids and/or azathioprine or 6-mercaptopurine or who are intolerant to such therapies.<sup>1</sup> With this approval, HUMIRA offers pediatric patients with moderately to severely active ulcerative colitis the first subcutaneous anti-TNF therapeutic option.<sup>1</sup>

“Ulcerative colitis is a miserable illness when it is not well controlled, and it has a significant impact on the lives of children and adolescents. When the disease is active, it is disabling and embarrassing, and affects how children can engage in their normal lives with peers and at school. Although we are able to treat a lot of children who have ulcerative colitis today, there is still a group of children and adolescents that we cannot help as well as we would like, which is why we do need access to new therapies,” said Dr. Anne Griffiths, Co-Lead, Inflammatory Bowel Disease Centre at the Hospital for Sick Children.

Ulcerative colitis is characterized by inflammation of the large intestine with symptoms ranging from mild to severe bowel urgency and bowel incontinence as well as weight loss and fatigue.<sup>4,5</sup> It remains a lifelong condition that is not adequately controlled in many patients, underscoring the need for more treatment options.<sup>3,4</sup> Children with ulcerative colitis may fail to develop or grow properly due to malabsorption of nutrients by the diseased bowel.<sup>5</sup> Significant unmet needs remain in moderate to severe pediatric ulcerative colitis, compared to adults, as pediatric patients tend to have more extensive disease often causing significant illness in children.<sup>4,6</sup>

Cal Spellman, who is now 17, remembers getting diagnosed when he was 11 years old. “It was very scary for me. As a kid, it can be intimidating when a doctor says you have a chronic illness, and even though it is treatable, it can be hard to manage. I remember having a really difficult time when I was about 12. I was hospitalized twice, four months apart from each other. I was having uncontrollable symptoms, which is particularly hard for someone going through puberty, when you are feeling self-conscious about things. But for anyone who is newly diagnosed, know

that it does get better. It will be hard, but it is something you can manage, and it is possible to live a normal life," he explained.

"Canada has one of the highest rates of inflammatory bowel disease (IBD) in the world<sup>5</sup>. With the number of cases increasing in children, it is important that we continue to expand the number of pediatric treatment options available" said Susan Cowan, CEO of Crohn's and Colitis Canada. "Ulcerative colitis, one of the main forms of IBD, is an unpredictable disease often requiring medication to manage debilitating symptoms. The introduction of a new therapy for children living with ulcerative colitis is an important advancement."

"This approval marks an important milestone for children and adolescents living with ulcerative colitis, who often struggle to control this lifelong condition, particularly because pediatric patients tend to have more extensive disease," added Tracey Ramsay, Vice President and General Manager, AbbVie Canada. "AbbVie is proud of our heritage and dedication to discovering and delivering innovative therapies that help adults and children living with inflammatory bowel disease."

### **About the ENVISION I Phase 3 Study<sup>2,7</sup>**

The Health Canada approval is based on results from the ENVISION I study, a Phase 3, randomized, double-blind, multicenter study designed to evaluate the efficacy, safety and the pharmacokinetics of HUMIRA in pediatric patients (ages 4-17) with moderate to severe ulcerative colitis, administered subcutaneously.

The ENVISION I study showed that HUMIRA met the co-primary endpoints of clinical remission at week 8 and, among those who responded at week 8, clinical remission at one year (52 weeks).<sup>1,2</sup>

No new safety signals for HUMIRA were observed in this study.<sup>1,2</sup> In patients exposed to HUMIRA during the study, 23 percent experienced a serious adverse event.<sup>1,2</sup> The most frequently reported (greater than or equal to five percent) treatment-emergent adverse events during induction and maintenance periods were headache and ulcerative colitis.<sup>1,2</sup> No deaths, malignancies, active tuberculosis or demyelinating disease were observed in this study.<sup>1,2</sup>

More information on this trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02065557).

### **About HUMIRA**

HUMIRA resembles antibodies normally found in the body. It works by blocking TNF- $\alpha$ , a protein that, when produced in excess, plays a central role in the inflammatory responses of many immune-mediated diseases.

For further information, please see the HUMIRA Product Monograph available on [www.abbvie.ca](http://www.abbvie.ca).

## About AbbVie in Gastroenterology

AbbVie has focused on improving care in gastroenterology for more than 10 years. With a robust clinical trial program in inflammatory bowel disease (IBD), we are committed to cutting-edge research to drive exciting discoveries and developments in Crohn's disease and ulcerative colitis. By innovating, learning, and adapting, AbbVie aspires to eliminate the burden of IBD and make a long-term impact on the lives of people with IBD.

## 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](http://www.abbvie.ca) and [www.abbvie.com](http://www.abbvie.com). Follow [@abbviecanada](https://twitter.com/abbviecanada) on Twitter or find us on [Facebook](#), [LinkedIn](#) and [Instagram](#).

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