



News Release

YOUNG PATIENTS TO BENEFIT FROM HEALTH CANADA APPROVAL OF REMICADE®* FOR TREATMENT OF PEDIATRIC ULCERATIVE COLITIS

Canadian children six to 17 years old become the first worldwide to benefit from a new biologic treatment option approved for chronic inflammatory bowel disease

TORONTO, September 1, 2011 – Young Canadians living with the debilitating inflammatory bowel disease ulcerative colitis (UC) will now have access to a new treatment option with Health Canada's approval of REMICADE® (infliximab) for use in pediatric patients (age six to 17 years). REMICADE® has been approved for the treatment of UC in adults in Canada since 2006.

With this Health Canada approval, REMICADE® represents the first biologic approved for the treatment of pediatric UC. REMICADE® is indicated for the reduction of signs and symptoms, induction and maintenance of clinical remission and induction of mucosal healing, in pediatric patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy (i.e., aminosalicylate and/or corticosteroid and/or an immunosuppressant). The safety and efficacy of REMICADE® have not been established in UC patients less than six years of age.¹

Ulcerative colitis is a chronic inflammatory bowel disease affecting an estimated 88,500 Canadians, including an estimated 1,758 children under 20.^{2,3} While the overall clinical features, clinical course of disease and response to treatment are comparable in pediatric and adult populations with UC, pediatric disease is often more extensive and severe. Despite this, there are few approved therapeutic options for pediatric UC.^{4,5,6,7}

"Pediatric ulcerative colitis can be a serious condition. The approval of biologic therapy that can help in managing ulcerative colitis in children and adolescents is welcome news," said Dr. David Mack, Chief of Pediatric Gastroenterology, Hepatology & Nutrition at the Children's Hospital of Eastern Ontario in Ottawa. "REMICADE® has demonstrated efficacy in the treatment of pediatric UC as evidenced by the clinical trial results and has been used in the treatment of inflammatory bowel disease including adult and pediatric Crohn's disease for years."

The approval of REMICADE® for pediatric UC was supported by data from a pivotal Phase 3, randomized, open-label trial that assessed its safety and efficacy in 60 patients age six through 17 with moderately to severely active UC. Eligible patients had an inadequate response to treatment with conventional therapy (i.e. aminosalicylate and/or corticosteroid and/or an immunosuppressant).⁸

In the clinical study, patients were administered REMICADE® 5 mg/kg at weeks 0, 2, and 6. REMICADE® induced a clinical response after eight weeks in 73.3 per cent of the pediatric patients with UC according to the Mayo score, a 12-point clinical assessment and colonoscopy-based measure of disease activity, and the definition of induced clinical remission was met by 40 per cent of patients. Also after eight weeks, 68.3 per cent of patients enrolled in the study achieved mucosal healing and one third (33.3 per cent) had normal or inactive disease as measured by the Mayo endoscopy subscore.⁸

Patients who achieved clinical response at eight weeks (n=45) were randomized to REMICADE® maintenance therapy at two different levels; 5 mg/kg every eight weeks or every 12 weeks. At week 54, 38.1 per cent (8/21)

of those in the eight week group and 18.2 per cent (4/22) in the 12 week group were in remission, as measured by the Pediatric UC Activity Index (PUCAI).⁸

REMICADE[®] was generally well tolerated by the 60 pediatric patients in the study and the safety profile was consistent with that reported in other studies with REMICADE[®]. No deaths, malignancies, serious neurologic events, opportunistic infections, tuberculosis, serious infusion reactions, delayed hypersensitivity reactions or anaphylactic reactions were reported.⁸

“REMICADE[®] fills an important need for children and adolescents with ulcerative colitis, which is a very difficult disease for anyone, but particularly for young people,” added Dr. Mack. “It provides a medical option for some who have not responded to other medical therapies and, as such, is an important and effective therapeutic option.”

About Ulcerative Colitis

Ulcerative colitis (UC) is a chronic inflammatory bowel disease affecting an estimated 88,500 Canadians, including an estimated 1,758 children under 20.^{2,3} It is marked by the inflammation and ulceration of the mucosa lining of the colon and rectum. Tiny open sores, or ulcers, form on the surface of the lining, where they bleed and produce pus and mucus. Because the inflammation makes the colon empty frequently, symptoms typically include diarrhea (most often bloody) and crampy abdominal pain, often leading to weight loss, anemia and a host of secondary complications. When conventional treatments do not control the symptoms of the disease, it is estimated that as many as 25 to 33 per cent of UC patients will undergo a colectomy, which is a surgical removal of the colon.²

About REMICADE[®]

REMICADE[®] is a monoclonal antibody that specifically targets tumor necrosis factor (TNF)-alpha, which has been shown to play a role in Crohn's disease, rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, ulcerative colitis (UC), pediatric Crohn's disease, plaque psoriasis, fistulizing Crohn's disease and pediatric UC. The safety and efficacy of REMICADE[®] have been well established in clinical trials over the past 17 years and through commercial experience with more than 1.5 million patients treated worldwide.

REMICADE[®] is the only anti-TNF biologic therapy available as an intravenous (IV) administration and the only anti-TNF biologic administered directly by healthcare professionals in the clinic (called BioAdvance[®] clinics in Canada) or office setting. REMICADE[®] is a two-hour infusion administered every six or eight weeks (indication-dependent), following a standard induction regimen that requires treatment at weeks 0, 2 and 6. As a result, REMICADE[®] patients may require as few as six treatments each year as maintenance therapy.

REMICADE[®] Safety Information

REMICADE[®] is contraindicated in patients with severe infections such as sepsis, abscesses, tuberculosis and opportunistic infections, in patients with moderate to severe (NYHA Class III/IV) congestive heart failure, and in patients with a history of hypersensitivity to REMICADE[®], to other murine proteins, or to any of the excipients. Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation), invasive fungal infections, and other opportunistic infections have been observed in patients receiving REMICADE[®]. Some of these infections have been fatal. Patients must be evaluated for the risk of tuberculosis, including latent tuberculosis, prior to initiation of REMICADE[®]. Rare post-marketing cases of hepatosplenic T-cell lymphoma have been reported in patients treated with TNF blockers including REMICADE[®]. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers. The potential role of TNF-blocking therapy in the development of malignancies is not known. Please refer to the Product Monograph for complete prescribing information.¹

About BioAdvance[®]

With a network of specialized clinics across Canada, BioAdvance[®] strives to provide biologic treatment options coupled with a range of resources that ultimately empower patients in the management of their disease. BioAdvance[®] is also committed to continued medical research and innovation so that new solutions may be found to help fight the many debilitating diseases of the immune system. BioAdvance[®] is setting the standard of biologic care in Canada by advancing the science of biologics and, more importantly, by applying it to real

life. BioAdvance® makes it easy for healthcare professionals and patients who are being treated with REMICADE® to access information and resources to help them better manage their disease and optimize their overall experience. Finally, as a responsible corporate partner, BioAdvance® recognizes the need to partner with various stakeholders to offer better access, care and support to patients suffering from these diseases.

About Janssen Inc.

As a member of the Janssen Pharmaceutical Companies, Janssen Inc. is dedicated to addressing and solving the most important unmet medical needs in pain management, psychiatry, oncology, immunology, psoriasis, virology, anemia, attention deficit hyperactivity disorder, gastroenterology and women's health. Driven by our commitment to the passionate pursuit of science for the benefit of patients, we work together to bring innovative ideas, products and services to patients around the world.

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¹ REMICADE® Product Monograph, Janssen Inc., 2011.

² Crohn's and Colitis Foundation of Canada. The Burden of Inflammatory Bowel Disease (IBD) in Canada: Final Report and Recommendations. 2008: 34, 19-20. Available at:

http://www.cafc.ca/site/c.a1lRK4NLLhJ0E/b.6431205/k.884D/The_Burden_of_IBD_in_Canada.htm. Last accessed: August 22, 2011.

³ Fedorak RN, Wong K, and Bridges R. Canadian Digestive Health Foundation Public Impact Series. Inflammatory bowel disease in Canada: Incidence, prevalence, and direct and indirect economic impact. *Can J Gastroenterol*. 2010 Nov;24(11):65 1-5.

⁴ Langholz E, Munkholm P, Krasilnikoff PA, Binder V. Inflammatory bowel diseases with onset in childhood. Clinical features, morbidity, and mortality in a regional cohort. *Scand J Gastroenterol*. 1997;32(2):139-147.

⁵ Hyams J, Markowitz J, Lerer T, et al. The natural history of corticosteroid therapy for ulcerative colitis in children. *Clin Gastroenterol Hepatol*. 2006;4(9):1118-1123.

⁶ Sauer CG, Kugathasan S. Pediatric Inflammatory Bowel Disease: Highlighting pediatric differences in IBD. *Gastroenterol Clin N Am*. 2009;38:611-628.

⁷ Van Limbergen J, Russell RK, Drummond HE, et al. Definition of phenotypic characteristics of childhood-onset inflammatory bowel disease. *Gastroenterology*. 2008;135(4):1114-1122.

⁸ Hyams et al. A Randomized, multicentre, open-label phase III study to evaluate the safety and efficacy of infliximab in pediatric patients with moderate to severe ulcerative colitis. Presented at the Digestive Disease Week, 7-11 May 2011, Chicago, IL, USA.