News Release

Media Contact: Jennifer McCormack
Office: (416) 382-5121

Investor Contact: Stan Panasewicz
Office: (732) 524-2524

Investor Contact: Louise Mehrotra
Office: (732) 524-6491

STUDY SHOWS SIMPONI®* INDUCED AND MAINTAINED CLINICAL RESPONSE IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

Findings from Two Pivotal Studies Published in Gastroenterology

Toronto, ON, February 5, 2014 – Janssen Inc. announced today that the results of the two pivotal clinical studies from **P**rogram of **U**lcerative Colitis **R**esearch **S**tudies **U**tilizing an **I**nvestigational **T**reatment (PURSUIT) have been published in *Gastroenterology*. The studies evaluate SIMPONI® (golimumab) induction and maintenance therapy in anti–tumor necrosis factor (TNF) naïve adults with moderate to severe ulcerative colitis (UC), who had an inadequate response to or had failed to tolerate conventional treatments. According to findings from the PURSUIT Induction and PURSUIT Maintenance studies, a greater proportion of patients who received subcutaneous (SC) SIMPONI® at weeks 0 and 2 achieved clinical response at week 6[1] and maintained clinical response with every-4-week SC SIMPONI® through week 54 compared to the placebo group.[2]

“Treatment with subcutaneous golimumab induces and maintains clinical response, induces clinical remission, and improves endoscopic appearance of the mucosa during induction, which may improve quality of life for Canadian adult patients with moderate to severe ulcerative colitis,” said Dr. Brian Feagan**, Professor of Medicine and Epidemiology and Biostatistics at the Western University in London, Ontario, and an expert in the field of inflammatory bowel disease. “Results of the Phase 3 PURSUIT trials further support golimumab as a proven treatment option for UC patients who have had an inadequate response to conventional therapy.”

In the Phase 3 portion of the PURSUIT Induction study, 51 per cent of patients who received SIMPONI® 200 mg/100 mg at weeks 0 and 2 and 55 per cent of patients who received SIMPONI® 400 mg/200 mg at weeks 0 and 2 met the primary endpoint of clinical response at week 6 compared to 30 per cent of patients in the placebo group.[3] Additionally, according to results from the PURSUIT Maintenance study, 47 per cent of patients who received SIMPONI® 50 mg and 50 per cent of patients who received SIMPONI® 100 mg every 4 weeks maintained continuous clinical response through week 54 compared with 31 per cent in the placebo group, meeting the study’s endpoint (patients who maintained clinical response through week 54 had no loss of response at any visit in PURSUIT Maintenance study and were considered to be in a state of continuous clinical response).[4]

Additional Findings

PURSUIT Induction Study[5]
At week 6 of the Phase 3 portion of the PURSUIT Induction study, significantly greater results were achieved for the major secondary endpoints in the SIMPONI® 200 mg/100 mg and SIMPONI® 400 mg/200 mg treatment groups compared with placebo, including:

- Clinical remission: 18 per cent, 18 per cent and six per cent, respectively ($P < 0.0001$)
- Mucosal healing: 42 per cent (P = .0014), 45 per cent ($P = 0.0001$) and 29 per cent, respectively
- Mean change from baseline in IBDQ scores: 27 points, 27 points and 15 points, respectively ($P < 0.0001$)

PURSUIT Maintenance Study[6]
Secondary endpoints in the PURSUIT Maintenance study are outlined below:

Secondary endpoints		SIMPONI® 100 mg	SIMPONI® 50 mg	Placebo
Clinical remission (at both week 30 and week 54)		28 per cent (P value = 0.004)	23 per cent	16 per cent
Mucosal healing (at both week 30 and week 54)		42 per cent (P value = 0.002)	42 per cent	27 per cent
Clinical remission (at both week 30 and week 54 among patients in clinical remission at baseline)		39 per cent	37 per cent	24 per cent
Corticosteroid-free clinical remission (at week 54) among patients receiving concomitant corticosteroids at baseline		23 per cent	28 per cent	18 per cent

Safety Information

Through week 6 of the PURSUIT Induction study, the incidences of serious adverse events (AEs) were similar, 3 per cent in the combined SIMPONI®-treated groups and 6 per cent in the placebo group. The only serious infection reported by more than one patient was pneumonia (one SIMPONI® 200 mg/100 mg and one placebo patient). One death was reported in the SIMPONI® 400 mg/200 mg treatment group. Through week 54 of the PURSUIT Maintenance study, serious AEs were reported in 6.7 per cent, 8.4 per cent and 14.7 per cent of all treated patients receiving placebo, SIMPONI® 50 mg and SIMPONI® 100 mg, respectively. The only serious infection reported by more than one patient was appendicitis, which was reported in three patients receiving SIMPONI® 100 mg. Three deaths were reported through week 54 in the SIMPONI® 100 mg maintenance group. The overall safety of SIMPONI® in the treatment of UC is consistent with the safety profile of SIMPONI® in other approved indications.

About PURSUIT

The Program of Ulcerative Colitis Research Studies Utilizing an Investigational Treatment (PURSUIT) included Phase 3 multicentre, randomized, double-blind, placebo-controlled studies to evaluate the efficacy and safety of induction and every-4-week maintenance regimens of SIMPONI® in adults with moderately to severely active UC. All trial patients had an inadequate response to or had failed to tolerate one or more of the following conventional therapies: oral 5-aminosalicylates (5-ASA), oral corticosteroids, azathioprine (AZA), and/or 6-mercaptopurine (6-MP); or were corticosteroid dependent (i.e., an inability to taper corticosteroids without recurrence of UC symptoms). Study participants were naïve to treatment with TNF inhibitors and had a baseline Mayo score between 6 and 12 and endoscopic subscore greater than or equal to 2.

The PURSUIT SC-Induction trial had an adaptive design with a Phase 2 dose finding portion followed by a dose-confirming Phase 3 component to assess the safety and efficacy of the selected SIMPONI® induction regimens. Patients were randomized to receive SC injections of placebo, SIMPONI® 100 mg/50 mg (prior to dose selection only), SIMPONI® 200 mg/100 mg or SIMPONI® 400 mg/200 mg at weeks 0 and 2. The primary endpoint was clinical response (decrease from baseline in the Mayo score ≥ 30% and ≥ 3 points, accompanied by either a rectal bleeding subscore of 0 or 1 or a decrease from baseline in the rectal bleeding subscore ≥1) at week 6. Major secondary endpoints included clinical remission, mucosal healing and a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) scores at week 6. Overall, 1,065 patients were randomized in the study, 774 of these patients were randomized into the Phase 3 component of the study.

The PURSUIT-Maintenance trial target population included patients who responded to induction treatment with SIMPONI® (optional: PURSUIT-SC and PURSUIT-IV). Patients in the target population were randomized to placebo or SC injections of SIMPONI® 50 mg or 100 mg every 4 weeks through week 52. Patients were assessed for UC disease activity using the Mayo score at weeks 30 and 54 and by partial Mayo score every 4 weeks. The primary endpoint was maintenance of clinical response through week 54 among SIMPONI®-induction responders. Major secondary endpoints of the maintenance study included clinical remission and mucosal healing at both weeks 30 and week 54; clinical remission at both weeks 30 and 54 among patients who were in clinical remission at week 0 of the maintenance trial; and corticosteroid-free clinical remission at week 54 among patients receiving concomitant corticosteroids at week 0 of the maintenance study.

About SIMPONI® (golimumab)

First approved by Health Canada in April 2009, SIMPONI®, in combination with methotrexate, is also indicated for reducing signs and symptoms and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA), as well as inhibiting the progression of structural damage in adult patients with moderately to severely active RA who had not previously been treated with methotrexate. SIMPONI® is also approved for reducing signs and symptoms, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active psoriatic arthritis, as well as reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapies. In September 2013, SIMPONI® was also indicated to reduce signs and symptoms, induce clinical remission, achieve sustained clinical remission in induction responders and improve endoscopic appearance of the mucosa during induction in adult patients with moderately to severely active UC who have had an inadequate response to, or have medical contraindications for, conventional therapy.[7]

SIMPONI® can lower the body's ability to fight infections. Serious infections, including sepsis, tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by the bacteria listeria) and opportunistic infections (such as systemic fungal and bacterial infections) have been reported in patients receiving SIMPONI® and other similar medicines, and in some cases have been fatal.

Please refer to the SIMPONI® Product Monograph for additional safety information, including information regarding malignancies, congestive heart failure, neurologic events and hematologic warnings, and for complete prescribing information available at www.janssen.ca/product/187.

Canadians living with UC and prescribed treatment with SIMPONI® will receive instruction and support from the BioAdvance®* Network of clinics, located in centres across Canada, or through home injection services delivered by BioAdvance®-qualified healthcare professionals.

About Ulcerative Colitis

Ulcerative colitis is a chronic inflammatory bowel disease (IBD) marked by ulcers in the lining of the colon.[8] Canada has among the highest incidence of people with IBD, including Crohn's disease and UC, in the world. It is estimated that there are over 230,000 individuals living with IBD in Canada, including over 100,000 people living with UC.[9] Symptoms of UC may include: bloody diarrhea, mild fever, abdominal pains and cramps, fatigue, loss of appetite, weight loss, and pain and swelling in the joints.[10] UC can have a range of implications for people's quality of life, including a negative psycho-social impact and a substantial personal burden.[11]

About Janssen Inc.

As part of the Janssen Pharmaceutical Companies of Johnson & Johnson, 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.

# # #

* All trademark rights used under license.
** Dr. Brian Feagan was not compensated for any media work. He has been a paid consultant to Janssen Inc.

References:

[1] Sandborn et al. "Subcutaneous golimumab induces clinical response and remission in patients with moderate-to-severe ulcerative colitis", *Gastroenterology* January 2014; 146: 85-95. Page 93.
[2] Sandborn et al. "Subcutaneous golimumab maintains clinical response in patients with moderate-to-severe ulcerative colitis", *Gastroenterology* January 2014; 146: 96-109. Page 96.
[3] Sandborn et al. "Subcutaneous golimumab induces…" Page 85.
[4] Sandborn et al. "Subcutaneous golimumab maintains…" Page 96.
[5] Sandborn et al. "Subcutaneous golimumab induces…" Page 92.
[6] Sandborn et al. "Subcutaneous golimumab maintains…" Page 103.
[7] SIMPONI® Product Monograph, Janssen Inc., 2013. Available at www.janssen.ca/product/187
[8] "The Impact of Inflammatory Bowel Disease (IBD) in Canada - 2012 Final Report and Recommendations," Crohn's and Colitis Foundation of Canada, accessed May 3, 2013, http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf
[9] "The Impact of Inflammatory Bowel Disease (IBD) in Canada - 2012 Final Report and Recommendations," Crohn's and Colitis Foundation of Canada, accessed May 3, 2013, http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf
[10] "The Impact of Inflammatory Bowel Disease (IBD) in Canada - 2012 Final Report and Recommendations," Crohn's and Colitis Foundation of Canada, accessed May 3, 2013, http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf
[11] "The Impact of Inflammatory Bowel Disease (IBD) in Canada - 2012 Final Report and Recommendations," Crohn's and Colitis Foundation of Canada, accessed May 3, 2013, http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf