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HEALTH CANADA ISSUES A NOTICE OF COMPLIANCE FOR SIMPONI® AS THE FIRST AND ONLY TREATMENT INDICATED FOR NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

Research shows SIMPONI® improves symptoms and physical function[1]

TORONTO, ON (June 23, 2016) — Janssen Inc. today announced Health Canada has approved SIMPONI® (golimumab) for the treatment of adults with severe active non-radiographic axial spondyloarthritis (nr-AxSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence who have had an inadequate response to or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). This is the fifth indication for SIMPONI® in Canada, which was approved originally by Health Canada in 2009 for adults living with moderately to severely active rheumatoid arthritis (RA).[2]

“This new indication for SIMPONI® is an important milestone for rheumatologists and their patients as we have seen a positive response to this treatment in those living with other inflammatory and rheumatic diseases,” said Dr. Nigil Haroon, a Clinician Scientist and Staff Rheumatologist at University Health Network*. “Non-radiographic axial spondyloarthritis is a very complex disease where early detection and treatment are important to effectively manage the condition and help improve quality of life for patients.”

The Health Canada approval of SIMPONI® for patients with nr-AxSpA is based on data from the Phase 3 GO-AHEAD trial. Treatment with SIMPONI® every four weeks resulted in significant improvements in the signs and symptoms of the disease through week 16 as demonstrated by the proportion of patients with an Assessment in Ankylosing Spondylitis (ASAS) 20 response, the primary endpoint of the study. At week 16, 71.1 per cent of patients treated with SIMPONI® achieved an ASAS 20 response, compared with 40.0 per cent of patients receiving the placebo ($P < 0.0001$).[3] Further, similar improvements in ASAS 20 were seen in the subpopulation of patients with elevated CRP and/or evidence of sacroiliitis on MRI at baseline.[4]

Adverse events occurred in 41 per cent and 47 per cent of patients receiving SIMPONI® and placebo, respectively. SIMPONI® was generally well-tolerated in the study, and its safety profile was consistent with the known safety profile of SIMPONI® when used for other indications.[5]

For more information visit www.janssen.com/canada or the SIMPONI® Product Monograph.

About Spondyloarthritis

Spondyloarthritis (SpA) describes a group of inflammatory arthritis diseases with common features, including inflammation of the spine, eyes, skin and gastrointestinal tract.[6] Axial Spondyloarthritis (AxSpA), a subset of SpA, affects the spine and sacroiliac joints (the joints between the pelvis and the sacrum or base of the spine).[7] AxSpA includes ankylosing spondylitis (AS) and nr-AxSpA.[8] AS describes the condition where some of the joints and bones of the spine become fused together because of inflammation,[9] resulting in pain and stiffness in the back.[10] Not all cases of nr-AxSpA turn out to be AS.[11]

About SIMPONI® (golimumab)[12]
SIMPONI® is a human monoclonal antibody that targets and neutralizes excess tumor necrosis factor (TNF)-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage and tissue.

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® also is 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 2013, SIMPONI® received approval for the treatment of moderately to severely active ulcerative colitis (UC).

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), opportunistic infections (such as systemic fungal and bacterial infections) and malignancies, have been reported in patients receiving SIMPONI® and other similar medicines, and in some cases have been fatal.

SIMPONI® is available either through the SmartJect® autoinjector/prefilled pen or a prefilled syringe as a subcutaneously administered injection.

About the Janssen Pharmaceutical Companies
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/canada. Follow us at @JanssenCanada.

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**Dr. Haroon was not compensated for any media work. He has been a paid consultant to Janssen Inc.*

References

[1] J. Sieper, et al. A Randomized, Double-Blind, Placebo-Controlled, Sixteen-Week Study of Subcutaneous Golimumab in Patients With Active Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology* Vol. 67, No. 10, October 2015, pp 2702–2712.
[2] SIMPONI product monograph. Janssen Inc. June 23, 2016.
[3] J. Sieper, et al. A Randomized, Double-Blind, Placebo-Controlled, Sixteen-Week Study of Subcutaneous Golimumab in Patients With Active Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology* Vol. 67, No. 10, October 2015, pp 2702–2712.
[4] Ibid.
[5] Ibid.
[6] Canadian Spondylitis Association. http://www.spondylitis.ca/spondyloarthritis/what-is-spondyloarthritis/. Accessed May 18, 2016.
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[10] The Arthritis Society. http://arthritis.ca/getmedia/cf8729ed-4482-48af-9170-5cf5f8475f63/Ankylosing-Spondylitis.pdf?ext=.pdf. Accessed May 18, 2016.
[11] Canadian Spondylitis Association. http://www.spondylitis.ca/spondyloarthritis/facts-figures/. Last accessed May 2, 2016.
[12] SIMPONI product monograph. Janssen Inc. June 23, 2016.