News Release

For Consumer Media/General Public

ADDITIONAL TREATMENT OPTION – TREMFYA® – NOW AVAILABLE ON THE PBS FOR AUSTRALIANS WITH ACTIVE PSORIATIC ARTHRITIS

SYDNEY, AUSTRALIA, 1 JULY 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that TREMFYA® (*guselkumab*) is now available on the Pharmaceutical Benefits Scheme (PBS) for adults with active Psoriatic Arthritis (PsA) who have had an inadequate response to, or are intolerant to, prior disease-modifying antirheumatic drug (DMARD) therapy.[1]

PsA is a chronic auto-immune disorder that causes inflammation in the joints and surrounding tissues, leading to pain, stiffness and swelling, as well as fatigue, making it difficult to carry out everyday activities.[2,3] There is currently no cure for PsA, and without early recognition, diagnosis and effective treatment, the disease can continue to progress.[2,3]

"Psoriatic arthritis is a complex, life-long condition that is common in people who have psoriasis," said Professor Peter Nash, Rheumatologist. "Despite available treatments, many people living with the condition continue to experience debilitating symptoms that can impact their mobility and quality of life. While the disease journey and symptoms will vary from person to person, data suggests that more than a quarter of people with active PsA who discontinue their treatment do so due to side effects or lack of effectiveness,[4] highlighting the need for additional treatment options."

PsA affects men and women equally and while it commonly appears between the ages of 30 and 50, it can develop at any time.[5] Though the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[2]

TREMFYA works by neutralising the activity of a protein called IL-23,[6] a naturally occurring cytokine that is involved in inflammatory and immune responses associated with the symptoms of PsA.[3]

"Janssen is proud to provide an additional treatment option for patients living with this debilitating, and at times distressing condition," said Biljana Naumovic, Managing Director, Janssen Australia and New Zealand. "The successful inclusion of TREMFYA on the PBS reinforces our ongoing commitment to develop, and make broadly available, innovative biologic medicines and tailored solutions that address the unmet needs of people living with immune-mediated diseases like PsA."

TREMFYA was included in the Australian Register of Therapeutic Goods (ARTG) for use in adults with active PsA in January 2021. The approved dose for adults with active PsA is 100mg at week 0, week 4, and every 8 weeks thereafter, administered by subcutaneous injection. It is approved for use alone or in combination with a conventional synthetic disease-modifying antirheumatic drug (csDMARD) such as methotrexate.[6]

-ENDS-

About Psoriatic Arthritis (PsA)

PsA is an inflammatory disease of the joints in which psoriasis usually occurs in association with arthritis. Inflammation occurs where the bone, tendon and ligament meet, and this can include severe inflammation in fingers and toes and pain in the spine, hips and shoulders, as well as the skin lesions associated with psoriasis.[2,3,5]

About TREMFYA®

Developed by Janssen, TREMFYA is the first Therapeutic Goods Administration (TGA) approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.

In Australia, TREMFYA is indicated for the treatment of adult patients with active psoriatic arthritis, who have had an inadequate response to, or are intolerant to prior DMARD therapy. TREMFYA is also indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[6]

Side effects can be reported directly to the treating physician or with the Therapeutic Goods Administration via www.tga.gov.au/reporting-problems.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/australia. Follow on Twitter @JanssenANZ. Janssen-Cilag Pty Ltd is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Consumer Medicines Information is available at:

https://www.janssen.com.au/tremfya_cmi

PBS Information: Authority Required. Refer to PBS Schedule for full details.

References

[1] PBS – https://www.pbs.gov.au/

[2] Arthritis Australia (2019). Taking control of your Psoriatic Arthritis. Available at: https://arthritisaustralia.com.au/wordpress/wp-content/uploads/2021/03/Psoriatic-Arthritis-WEB-2019-Mar21-Update.pdf Accessed: June 2021.

[3] Belasco J, Wei N. Psoriatic Arthritis: What is Happening at the Joint? *Rheumatol Ther* 2019;6:305-315.

[4] Tymms K, Kelly A, Bird P *et al*. Int J Rheum Dis. 2018 Feb;21(2):510-516. doi: 10.1111/1756-185X.13127.

[5] National Psoriasis Foundation (US). About Psoriatic Arthritis. Available at: https://www.psoriasis.org/about-psoriatic-arthritis/ Accessed: June 2021.

[6] TREMFYA® GUSELKUMAB Australian Product Information. Last updated January 2021.

Note to editors: Professor Peter Nash has been involved in clinical trials sponsored by Janssen. He has received honoraria as a member of advisory boards for Janssen. In relation

to this Janssen media announcement, no compensation was provided to Professor Peter Nash, and the opinions expressed are his own. Professor Peter Nash has been briefed by Janssen on the approved use of this product.

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