FOR UK NATIONAL HEALTH MEDIA, MEDICAL AND TRADE MEDIA ONLY
Under strict embargo until publication of decision on SMC website, after 2:00pm BST 9 August 2021

Media Contact:
Preetika Ramjoorawon
Phone: +44 (0) 7920 417 930
Email: PRamjoor@ITS.JNJ.com

SCOTTISH MEDICINES CONSORTIUM (SMC) ACCEPTS TREMFYA®▼ (GUSELKUMAB), THE FIRST IL-23 p19 INHIBITOR TREATMENT, FOR ACTIVE PSORIATIC ARTHRITIS (PsA)

TREMFYA® (guselkumab) is the first selective IL-23 p19 subunit inhibitor accepted for use within NHS Scotland for both the treatment of moderate to severe plaque psoriasis (PsO) and eligible patients with active psoriatic arthritis (PsA)[1]

High Wycombe, UK, 9 August 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson welcomes the Scottish Medicines Consortium (SMC) acceptance of TREMFYA® (guselkumab), alone or in combination with methotrexate (MTX), within NHS Scotland as an option for treating active psoriatic arthritis (PsA) in adult patients who have failed to respond or who have been intolerant to prior conventional systemic therapies (including ciclosporin, methotrexate and phototherapy). Specifically, guselkumab will be available to adults with active PsA:

- whose disease has not responded adequately or who could not tolerate two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received a biologic DMARD therapy (biologic-naïve population);
- whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and
- patients in whom TNF inhibitors are contraindicated or not tolerated.[2]

PsA is a progressive and multifaceted, chronic, immune-mediated inflammatory disease. It is characterised by debilitating joint damage and inflammation in addition to enthesitis, dactylitis, axial disease, and the skin lesions associated with PsO. The pain, stiffness and swelling of the joints and connective tissue can be severe and cause everyday tasks to become difficult.[3,4] As many as 160,000 people in Scotland have PsO and over 48,000 of these may go on to develop PsA, but there is currently no known cure.[5,6] In addition, more

than half of people with PsA also live with additional conditions, such as cardiovascular disease, osteoporosis, inflammatory bowel disease or depression.[7,8]

Guselkumab is the first and only approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. IL-23 is an important driver of the progression of inflammatory diseases including PsO and PsA, among others.[9,10]

"Psoriatic arthritis is a lifelong disease that can have a negative impact on a person physically and mentally, and can carry a burden for the individuals with the disease, their families and society. At present, we do not have a sufficient number of medicines with different modes of action to manage this lifelong disease effectively. The arrival of guselkumab, which shows benefits in treatment of the skin, the joints and the tendons, in people with psoriatic arthritis is a very welcome addition to our armamentarium." said Professor Iain B McInnes*, Professor of Rheumatology, Vice-Principal and Head of College of Medical, Veterinary and Life Sciences at the University of Glasgow.

This SMC advice is based on results from the DISCOVER-1 and DISCOVER-2 Phase 3 pivotal clinical trials, which assessed safety and efficacy of guselkumab 100 mg dosed every 8 weeks (q8w) and every 4 weeks (q4w) in adult patients with active PsA. DISCOVER-1 evaluated 381 participants with active PsA who had an inadequate response to standard therapies, including participants (~30%) previously treated with anti-tumour necrosis factor (TNF) alpha biologics.[11] DISCOVER-2 included 739 patients who were biologic-naïve only and had an inadequate response to standard therapies.[10] Data from these studies were published in 2020 in The Lancet (24-weeks duration; DISCOVER-1, DISCOVER-2).[10,11]

"We welcome the decision from the SMC to make guselkumab available to people living with PsA in Scotland, who have not yet tried a biological DMARD therapy, with or without methotrexate. Guselkumab is not only a new treatment option for people with active PsA, but also the first IL-23 p19 inhibitor to be approved as a treatment for PsA," said Amanda Cunnington, Patient Access and Health Affairs Director, Janssen-Cilag Limited. "*This decision further supports our commitment to ensuring patients living with PsA have access to new treatment options. We will work closely with the SMC and NHS Scotland to ensure that guselkumab will be available for use in clinical practice as quickly as possible for eligible*

patients who may benefit from this treatment."

In both DISCOVER-1 and DISCOVER-2, guselkumab had a favourable risk-benefit profile, and observed adverse events (AEs) were generally consistent with previous studies of guselkumab and those included in the current Summary of Product Characteristics. In DISCOVER-1 and DISCOVER-2, serious adverse events up to week 24 in q8w treatment arms (3% and 1% respectively for DISCOVER-1 and DISCOVER-2) and q4w treatment arms (0% and 3% respectively) were comparable to those in the placebo arms (4% and 3% respectively). In DISCOVER-2, less than 1% of patients experienced serious infections following guselkumab treatment, and no patient experienced serious infections following guselkumab treatment in DISCOVER-1. There were no reported deaths in guselkumab-treated patients and no guselkumab-treated patient had inflammatory bowel disease, opportunistic infections such as tinea or candida or active tuberculosis.[10,11]

Guselkumab is already accepted by the SMC as a clinical and cost-effective option for the treatment of eligible patients with moderate to severe plaque PsO.[1]

ENDS

*Professor McInnes has received consultancy honoraria from Janssen. He has not been compensated for any media work.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterised by peripheral joint inflammation, enthesitis (pain where the bone, tendon and ligament meet), dactylitis (severe inflammation of the finger and toe joints), axial disease, and the skin lesions associated with PsO.[4,12,13] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[8] Studies show that between 10% to 30% of people with PsO also develop PsA.[6] The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 25 and 50, but can develop at any time.[14] Nearly half of patients with PsA experience moderate fatigue and about 30% suffer from severe fatigue as measured by the modified fatigue severity scale.[15] 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.[16]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is a fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.[17] Guselkumab is approved as a prescription medicine in the UK for the treatment of adult patients with moderate to severe plaque PsO who are candidates systemic therapy. It also has approved indications in PsO in the EU, US, Canada, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque PsO who may benefit from systemic therapy, or phototherapy (treatment using ultraviolet [UV] light).[17]

Guselkumab was approved by the European Commission in November 2020 for adults with active PsA who have been intolerant to a prior DMARD therapy. Guselkumab is also approved for PsA in the US, Canada, Japan, Brazil, Ecuador, and Taiwan. The PsA approval was based on results from the DISCOVER-1 and DISCOVER-2 studies, which showed guselkumab reached each study's primary endpoint of ACR 20 response at 24 weeks. Complete study results were published in The Lancet.[10,11]

IL-23 is an important driver of the progression of inflammatory immune-mediated diseases such as PsO and PsA.[9,10] In the UK, guselkumab is administered as a 100 mg SC injection once every 8 weeks, after starter doses at weeks 0 and 4 for both PsO and PsA; with 100 mg SC doses every 4 weeks considered in patients with PsA who are at high risk for joint damage according to clinical judgement.[17]

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA®.

Important safety information[18]

Very common (≥10%) and common AEs (≥ 1% to < 10%) in controlled periods of clinical studies with guselkumab were respiratory tract infections, increased transaminases, headache, diarrhoea, arthralgia and injection site reactions. Uncommon AEs (≥ 0.1% to

< 1%) observed were herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash.

In PsA clinical studies, an increased incidence of liver enzyme elevations was observed in patients treated with guselkumab q4w compared to patients treated with guselkumab q8w or placebo.

When prescribing guselkumab q4w in PsA, it is recommended to evaluate liver enzymes at baseline and thereafter according to routine patient management. If increases in ALT or AST are observed and drug-induced liver injury is suspected, guselkumab should be temporarily interrupted until this diagnosis is excluded.

Please refer to the full Summary of Product Characteristics for further safety information for guselkumab: https://www.medicines.org.uk/emc/product/9587/smpc.

▼ AEs should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected AEs related to this medicinal product. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. AEs should also be reported to Janssen-Cilag Ltd on 01494 567447 or at dsafety@its.jnj.com.

About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37) and DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)[10,11]

DISCOVER-1 is a randomised, double-blind, multicentre Phase 3 clinical trial evaluating the efficacy and safety of guselkumab administered by subcutaneous (SC) injection in participants with active PsA, including those previously treated with one or two biologic tumour necrosis factor inhibitors. DISCOVER-1 evaluated 381 participants and continued through approximately one year.

The study consisted of a screening phase of up to six weeks, a blinded active treatment phase of 52 weeks that included a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 52. It also included a safety follow-up phase of eight weeks after week 52 (week 52 to week 60; 12 weeks from the last administration of study agent at week 48 through to the final

visit in the safety follow-up phase). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

DISCOVER-2 is a randomised, double-blind, multi-centre Phase 3 clinical trial evaluating the efficacy and safety of guselkumab administered by SC injection in patients with active PsA. DISCOVER-2 evaluated 739 participants and continued through approximately two years.

The study consisted of a screening phase of up to six weeks, a blinded active treatment phase (approximately 100 weeks) that included a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 100. It also included a safety follow-up phase of 12 weeks after the last administration of study agent. Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations were performed in the study on a defined schedule.

Previously announced DISCOVER-1 and DISCOVER-2 data showed guselkumab demonstrated improvements in multiple clinical outcomes of PsA including joint symptoms, skin symptoms, soft tissue inflammation, physical function, axial-related disease, fatigue as measured by Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) Scale, and low rates of radiographic progression compared to placebo at week 24; these improvements were maintained in the active treatment phase through week 52.[10,11,18,19]

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/UK.

Follow us at www.Twitter.com/JanssenUK.

Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU, Janssen-Cilag Limited and Janssen Research & Development, LLC, are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding ongoing and planned development efforts involving TREMFYA® (guselkumab) as a treatment for adult patients with active psoriatic arthritis. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

# # #

References

[1] Scottish Medicines Consortium Medicines advice for guselkumab (Tremfya®). Available at: https://www.scottishmedicines.org.uk/medicines-advice/guselkumab-tremfya-fullsubmission-134018/ Accessed August 2021.
[2] Scottish Medicines Consortium Medicines advice for guselkumab (Tremfya®). Available at: LINK TO BE INSERTED Accessed August 2021.
[3] Busse K, Liao W. Which Psoriasis Patients Develop Psoriatic Arthritis? *Psoriasis Forum* 2010;16(4):17–25.
[4] Belasco J, Wei N. Psoriatic Arthritis: What is Happening at the Joint? *Rheumatol Ther* 2019;6(3):305–315.
[5] Healthcare Improvement Scotland. Treating psoriasis and psoriatic arthritis. https://www.sign.ac.uk/media/1185/pat121.pdf Accessed August 2021.
[6] Lenman, M. *et al.* Diagnosis and management of psoriatic arthropathy in primary care. *British Journal of General Practice*. 2014; 64 (625): 424-425.
[7] Arthritis Foundation. Metabolic Comorbidities of Psoriatic Arthritis. Available at: https://www.arthritis.org/health-wellness/about-arthritis/related-conditions/other-diseases/metabolic-comorbidities-of-psoriatic-arthritis. Accessed August 2021.
[8] Haddad A and Zisman D. Comorbidities in Patients with Psoriatic Arthritis. *Rambam Maimonides Med* J 2017;8(1):e0004.
[9] Benson JM, *et al.* Discovery and Mechanism of Ustekinumab: A Human Monoclonal Antibody Targeting interleukin-12 and interleukin-23 for Treatment of Immune-Mediated Disorders. *MAbs* 2011;3:535–545.
[10] Mease PJ, *et al.* Guselkumab in Biologic-naive Patients with Active Psoriatic Arthritis (DISCOVER-2): A Double-blind, Randomised, Placebo-controlled Phase 3 Trial. *The Lancet* 2020;395(10230):1126–1136.
[11] Deodhar A, *et al.* Guselkumab in Patients with Active Psoriatic Arthritis who were Biologic-naive or had Previously Received TNFα Inhibitor Treatment (DISCOVER-1): a Double-blind, Randomised, Placebo-controlled Phase 3 Trial. *The Lancet* 2020;395(10230):1115–1125
[12] Creaky Joints. What is Enthesitis? Available at: https://creakyjoints.org/symptoms/what-is-enthesitis/. Accessed August 2021.
[13] Creaky Joints. What is Dactylitis? Available at: https://creakyjoints.org/symptoms/what-is-dactylitis/. Accessed August 2021.
[14] Versus Arthritis. All About Psoriatic Arthritis. Available at: https://www.versusarthritis.org/news/2020/january/all-about-psoriatic-arthritis/ Accessed August 2021
[15] Husted JA, *et al.* Occurrence and correlates of fatigue in psoriatic arthritis. *Annals of the Rheumatic Diseases* 2008;68(10):1553–1558.
[16] Cassell S & Kavanaugh A. Psoriatic arthritis: pathogenesis and novel immunomodulatory approaches to treatment. *J Immune Based Ther Vaccines*. 2005;3:6.
[17] Janssen-Cilag Ltd. Tremfya summary of product characteristics. Available at: https://www.medicines.org.uk/emc/product/9587/smpc Accessed August 2021.
[18] Ritchlin CT, *et al.* SAT0397 Guselkumab, an IL-23 Inhibitor that Specifically Binds to the IL23P19-Subunit, for Active Psoriatic Arthritis: One Year Results of a Phase 3, Randomized, Double-blind, Placebo-controlled Study of Patients who were Biologic-naïve or TNFA inhibitor-experienced. *Annals of the Rheumatic Diseases* 2020;79:1148-1149.
[19] Mcinnes I*, et al.* SAT0402 Efficacy and Safety of Guselkumab, a Monoclonal Antibody Specific to the P19-Subunit of Interleukin-23, Through Week 52 of a Phase 3, Randomized, Double-blind, Placebo-controlled Study Conducted in Biologic-naïve Patients with Active Psoriatic Arthritis. *Annals of the Rheumatic Diseases* 2020;79:1152-1153.

Electronic Signature Form

Code:	EM-70126
Name:	Tremfya PsA SMC Acceptance 2021 Press Release
Country:	United Kingdom
Product:	TREMFYA_UK°
Distribution Method:	Email
Audience:	Media
Project Owner:	Daniel Davis
Document Type:	Educational Material

I hereby certify that this material is in its final form and that, in my belief, it is in accordance with the requirements of the relevant local regulations and Code of Practice and is a fair and truthful presentation of the facts.

Signatory Approvals	
Signatories Approval	Tito Roccia EMEA Signatories 06-Aug-2021 19:58:00 GMT+0000