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**NICE RECOMMENDS TREMFYA®▼ (GUSELKUMAB) A FIRST-IN-CLASS TREATMENT  
FOR ACTIVE PSORIATIC ARTHRITIS (PsA)**

*TREMFYA® (guselkumab) is the first selective IL-23 p19 subunit inhibitor recommended in the UK for both the treatment of moderate to severe plaque psoriasis and eligible patients with active psoriatic arthritis (PsA)<sup>1</sup>*

**High Wycombe, UK, 28 May 2021** – The Janssen Pharmaceutical Companies of Johnson & Johnson welcomes the National Institute for Health and Care Excellence (NICE) positive Final Appraisal Document (FAD) recommending TREMFYA® (guselkumab) as a new option for treating active psoriatic arthritis (PsA) in adults who have not responded well to disease-modifying antirheumatic drug (DMARD) therapy or who cannot tolerate them, only if they have:

- Peripheral arthritis with three or more tender joints and three or more swollen joints
- Moderate to severe psoriasis (a body surface area of at least 3 percent affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10)
- Had two conventional DMARDs and at least one biological DMARD.<sup>2</sup>

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 psoriasis. The pain, stiffness and swelling of the joints and connective tissue can be severe and cause everyday tasks to become difficult.<sup>3,4</sup> According to estimates, up to 123,000 people in the UK live with PsA and up to 30 percent of those who live with psoriasis may go on to develop PsA but there is currently no known cure.<sup>5,6</sup> In addition, more than half of people with PsA also live with additional conditions, such as cardiovascular disease, osteoporosis, inflammatory bowel disease or depression.<sup>7,8</sup>

Guselkumab is the first 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 psoriasis and PsA, among others.<sup>9,10</sup>

*"Psoriatic arthritis is a disease that can lead to severe disability and irreversible damage to joints. Guselkumab provides a new treatment option for eligible patients that offers both symptom control as well as protection from long term joint damage. The recent NICE announcement is welcome news indeed, and a great addition to our existing treatment toolkit."* Commented Dr James Galloway, Consultant Rheumatologist, Reader and Deputy Head of the Centre for Rheumatic Diseases at King's College Hospital, London.

This recommendation is based on results from the DISCOVER-1 and DISCOVER-2 Phase 3 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.<sup>11</sup> DISCOVER-2 included 739 patients who were biologic-naïve only and had an inadequate response to standard therapies.<sup>10</sup> Data from these studies were published in 2020 in The Lancet (24-weeks; DISCOVER-1, DISCOVER-2).<sup>10,11</sup>

*"Guselkumab is not only a new treatment option for people with active psoriatic arthritis, but also the first IL-23 inhibitor to be approved as a treatment for PsA. While we are pleased that NICE, in its recommendation, has identified the benefits this treatment can bring to people who are severely affected by PsA, we recognise there is still an unmet need for a wider population of people living with this chronic condition."* said Amanda Cunnington, Patient Access and Health Affairs Director, Janssen-Cilag Limited. *"We will continue to collaborate with NICE to broaden access for all patients with PsA who could potentially benefit from guselkumab."*

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 prescribing information. 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 similar 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, active tuberculosis or anaphylactic or serum sickness-like reactions.<sup>10,11</sup>

Guselkumab is already recommended by NICE as a clinical and cost-effective option for the treatment of eligible patients with moderate to severe plaque psoriasis.<sup>1</sup> The FAD will form the basis of the final Technology Appraisal Guidance (TAG) issued to the NHS in England and Wales which is expected to be published in June 2021. Pending any appeals from key stakeholders, based on this positive recommendation, the NHS should make guselkumab available in England and Wales within three months of publication of the TAG.

## **ENDS**

\*Dr Galloway 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 psoriasis.<sup>4,12,13</sup> In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.<sup>8</sup> Studies show up to 30% of people with psoriasis (Pso) also develop PsA.<sup>5,6</sup> 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.<sup>14</sup> Nearly half of patients with PsA experience moderate fatigue and about 30% suffer from severe fatigue as measured by the modified fatigue severity scale.<sup>15</sup> 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.<sup>16</sup>

### **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.<sup>17</sup> Guselkumab is approved as a prescription medicine in the UK for the treatment of adult patients with moderate to severe plaque Psoriasis who are candidates for injections or pills (systemic therapy). It also has approved indications in Psoriasis in the EU, US, Canada, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque Psoriasis who may benefit systemic therapy, or phototherapy (treatment using ultraviolet [UV] light).<sup>17</sup>

Guselkumab was approved by the European Commission in November 2020 for adults with active Psoriasis who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. Guselkumab is also approved for Psoriasis in the US, Canada, Japan, Brazil, Ecuador, and Taiwan. The Psoriasis approval was based on results from DISCOVER-1 and DISCOVER-2, which showed guselkumab reached each study's primary endpoint of ACR 20 response at 24 weeks. Complete study results were previously published in *The Lancet*.<sup>10,11</sup>

IL-23 is an important driver of the progression of inflammatory immune-mediated diseases such as psoriasis and Psoriasis.<sup>9,10</sup> 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 plaque psoriasis and Psoriasis, with 100 mg SC doses every 4 weeks considered in patients with Psoriasis who are at high risk for joint damage according to clinical judgement.<sup>17</sup>

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

### **Important safety information**<sup>17</sup>

Very common ( $\geq 10\%$ ) and common AEs ( $\geq 1\%$ ) in controlled periods of clinical studies with guselkumab were respiratory tract infections, increased transaminases, headache, diarrhoea, arthralgia and injection site reactions. Uncommon AEs ( $\geq 0.1\%$ ) observed were herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash. Most were considered to be mild and did not necessitate discontinuation of study treatment.

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 full prescribing 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 [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) 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.

**About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37) and DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)**<sup>10,11</sup>

DISCOVER-1 is a randomised, double-blind, multicentre Phase 3 study 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 study 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.<sup>10,11</sup>

### **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](http://www.janssen.com/uk).

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Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU, 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](http://www.sec.gov), [www.jnj.com](http://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.*

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