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**News Release**

**Media Contact:**

Kevin Veninga  
Mobile: +31 6 1526 8214  
Email: [kveninga@its.jnj.com](mailto:kveninga@its.jnj.com)

**Investor Contact:**

Raychel Kruper  
Email: [investor-relations@its.jnj.com](mailto:investor-relations@its.jnj.com)

**New Real-World Data Show TREMFYA® (guselkumab) Was Associated With Clinically Meaningful Improvements in Patient-Reported Outcomes for Adults Living With Active Psoriatic Arthritis**

*People living with treatment-resistant active psoriatic arthritis reported meaningful improvements in pain, physical function and fatigue on guselkumab through six months*

*Additional pooled data from three clinical trials support the established efficacy of guselkumab in key psoriatic domains across those who were bio-naïve or TNFi-experienced*

**BEERSE, BELGIUM, 8 November 2023** – Janssen Pharmaceuticals, Inc., a Johnson & Johnson company, today announced new data from the CorEvitas Psoriatic Arthritis (PsA) and Spondyloarthritis Registry that showed a substantial proportion of people living with treatment-resistant active PsA and using TREMFYA® (guselkumab) in real-world settings reported meaningful improvements in pain, physical function and fatigue through six months.<sup>1</sup> Additionally, across the DISCOVER-1, DISCOVER-2 and COSMOS clinical trials, treatment with guselkumab was associated with higher rates of clinically meaningful improvements in a composite assessment of patient-reported pain, fatigue, physical function, skin problems and PsA-related depression than

placebo in the first assessment of the PsA 5-Thermometer Scale Domains (PsA-5T-Ds).<sup>2</sup>

Guselkumab is the only fully human selective interleukin (IL)-23p19-subunit inhibitor therapy approved for the treatment of adults living with active PsA.<sup>3,4</sup> These study results are among 24 company-sponsored abstracts being presented by Janssen at the American College of Rheumatology (ACR) Convergence 2023 meeting taking place in San Diego, CA, 10-15 November 2023.

“People living with active psoriatic arthritis who are treatment-resistant need options that improve debilitating symptoms of their disease, like pain, physical function and fatigue,” said Philip Mease, M.D., Swedish Medical Center/Providence St. Joseph Health and University of Washington in Seattle, Washington.<sup>a</sup> “It is important that we assess patient-reported outcomes in a real-world setting, ensuring that we address unmet needs for people living with this challenging disease.”

**CorEvitas data showed patients characterised by longstanding, treatment-resistant, active disease reported meaningful improvements in pain, physical function and fatigue.<sup>1</sup>**

In this analysis of the CorEvitas registry data,<sup>b</sup> substantial proportions of on-label guselkumab persisters<sup>c</sup> (n=90) reported clinically meaningful improvements from baseline (unadjusted nominal p values):<sup>1</sup>

- Among these registry participants who reported moderate levels of PsA-related pain prior to starting guselkumab (n=89, mean baseline score of 57 on a 0-100 mm visual analogue scale [VAS]), substantial proportions experienced clinically meaningful improvements in pain.<sup>1</sup> Thirty-eight percent reported a  $\geq 30$  percent reduction (n=33/86) and 40 percent reported a  $\geq 15$ -mm reduction (n=33/82).<sup>1</sup>
- Participants were evaluated for clinically meaningful improvements in overall joint and skin disease (n=84, mean baseline score of 50.3 VAS).<sup>1</sup> Forty-seven percent had a  $\geq 15$ -mm reduction (n=36/77) in the patient global assessment of arthritis and psoriasis.<sup>1</sup>

- Participants' physical function was also assessed (n=89, mean baseline score of 0.9 with Health Assessment Questionnaire Disability Index [HAQ-DI]).<sup>d,1</sup> Thirty percent (n=21/69) showed clinically meaningful improvements in physical function with HAQ-DI improvement of  $\geq 0.35$ .<sup>1</sup>
- Up to one-quarter of patients achieved the more stringent thresholds of response, generally representing a major response or minimal disease activity, including 26 percent (n=18/69) with patient global assessment score  $\leq 20$ -mm, 22 percent (n=19/86) with  $\geq 50$  percent reduction in pain, 18 percent (n=14/80) with pain score  $\leq 15$  mm and 10 percent (n=6/58) with HAQ-DI  $\leq 0.5$  (all nominal  $p < 0.001$ ).<sup>1</sup>
- Mean change (95 percent confidence interval [CI]) in PsA-related fatigue from baseline at six months was -8.8 (-14.9, -2.7; nominal  $p = 0.005$ ; based on component score of the Bath Ankylosing Spondylitis Disease Activity Index, 0-100 VAS; with a 56.5 baseline score [n=89]).<sup>1</sup>
- These aspects of psoriatic arthritis are often difficult to treat and are important contributors to health-related quality of life for people living with PsA.<sup>1</sup>

**Analysis of DISCOVER-1, DISCOVER-2 and COSMOS clinical trials supports established guselkumab efficacy across key PsA patient-reported outcomes.<sup>2</sup>**

In the first assessment of the PsA-5T-Ds<sup>e</sup> longitudinal construct validity, in people living with PsA who were bio-naïve or who had an inadequate response to one or two tumour necrosis factor inhibitors (TNFis),<sup>f</sup> this composite score of five patient-reported outcomes showed a strong correlation with the Psoriatic Arthritis Disease Activity Score (PASDAS), a validated instrument that encompasses most core PsA domains, and a good ability to discriminate between those with and without clinically meaningful improvements in disease activity and health-related quality of life.<sup>2</sup>

- PsA-5Ts is a simple multidimensional composite measure, assessing self-reported pain, fatigue, physical function, skin problems and depression, recently developed to measure overall health in people living with PsA and correlate with established composite measures.<sup>2</sup>

- Changes in PsA-5T-Ds score through week 24 correlated strongly with variations in PASDAS ( $r=0.7$ ;  $p<0.0001$ ) and moderately with variations in Disease Activity Index for PsA (DAPSA), clinical DAPSA and 36-Item short form survey (SF-36) physical component summary (PCS) scores ( $r=0.5$ ; all  $p<0.0001$ ).<sup>2</sup>
- Achievement of clinically meaningful improvement in PASDAS, DAPSA, clinical DAPSA and SF-36 PCS score through week 24 was associated with significantly greater improvements in PsA-5T-Ds score vs. nonachievement.<sup>2</sup>

“These new guselkumab results demonstrate our commitment to addressing symptoms that impact people living with active psoriatic arthritis, including depression, pain, fatigue, physical function and skin problems,” said Terence Rooney, M.D., Vice President, Rheumatology, Immunology Disease Area Leader, Janssen Research & Development, LLC. “It is critical that we evaluate patient-reported outcomes to truly understand the lived experiences of patients and better develop and provide treatments in psoriatic disease.”

#### **Editor’s Notes:**

- a. Dr. Philip Mease is a paid consultant for Janssen. He has not been compensated for any media work.
- b. This analysis includes registry patients who initiated on-label guselkumab use after 13 July 2020, and were on-label persisters.<sup>1</sup> Among 114 on-label guselkumab initiators with a six-month follow-up visit, 90 (79 percent) had persistent on-label guselkumab use.<sup>1</sup> On average, these patients had longstanding, treatment-resistant active PsA.<sup>1</sup>
- c. Guselkumab persisters were patients who received guselkumab post-Food and Drug Administration (FDA) approval and persisted with treatment through the six-month visit.<sup>1</sup>
- d. HAQ-DI is a patient questionnaire that assesses physical function and disability across rheumatic diseases.<sup>5</sup> HAQ-DI was measured on a scale of 0-3.<sup>1</sup>
- e. A PsA-5T-Ds score (range 0-100) was calculated based on the Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) scale, HAQ-DI, and question 28 (*‘Have you felt downhearted and depressed’*) of the 36-Item Short

Form Survey (SF-36) to assess fatigue, physical function, and depression, respectively, after 0-10 transformation; patient pain and skin disease activity were assessed with native 0-10 visual analogue scales.<sup>2</sup>

- f. Participants in DISCOVER-1 and DISCOVER-2 (D1 and D2; n=1120 ~90 percent bio-naïve) and COSMOS (n=285; inadequate response to one or two TNFi) had active PsA and were randomised to guselkumab 100 mg every four weeks (D1/D2 only); guselkumab 100 mg at week 0, week 4, at every eight weeks; or placebo.<sup>2</sup>

### **About CorEvitas**

The CorEvitas PsA/Spondyloarthritis (SpA) Registry is a prospective, observational registry for patients living with PsA or SpA in the United States under the care of a rheumatologist.<sup>1,6</sup> Response rates at six months were determined for established outcomes related to improvements or achievement of low levels of disease activity in patient-reported pain (0-100 mm visual analogue scale [VAS]), patient global assessment of arthritis and psoriasis (patient global assessment [PtGA]; 0-100 mm VAS), and HAQ-DI (0-3).<sup>1</sup> On average, patients had longstanding, treatment-resistant, active PsA.<sup>1</sup>

### **About DISCOVER-1 (NCT03162796)**

DISCOVER-1 was a Phase 3, multicentre, randomised, double-blind study evaluating the efficacy and safety of guselkumab administered by subcutaneous injection in participants with active PsA, including those previously treated with one to two TNFis.<sup>7</sup> DISCOVER-1 evaluated 381 participants who were randomised and treated.<sup>8</sup> The study consisted of a screening phase of up to six weeks, a blinded treatment of 52 weeks that included a placebo-controlled period from week 0 to week 24, and a blinded active treatment period from week 24 to week 52.<sup>7</sup> It also included a safety follow-up phase through week 60 (i.e., approximately 12 weeks from the last administration of the study agent at week 48).<sup>7</sup> Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.<sup>7</sup> The primary endpoint was response of ACR20 at week 24.<sup>7</sup>

### **About DISCOVER-2 (NCT03158285)**

DISCOVER-2 was a Phase 3, multicentre, randomised, double-blind study evaluating the efficacy and safety of guselkumab administered by subcutaneous injection in biologic-naïve patients with active PsA.<sup>9</sup> DISCOVER-2 evaluated 739 participants who were randomised and treated.<sup>10</sup> The study consisted of a screening phase of up to six weeks, a blinded treatment phase of approximately 100 weeks that included a placebo-controlled period from week 0 to week 24 and a blinded active treatment period from week 24 to week 100.<sup>9</sup> It also included a safety follow-up phase through week 112 (i.e., approximately 12 weeks after the last administration of study agent at week 100).<sup>9</sup> Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker and pharmacogenomics evaluations were performed in the study on a defined schedule.<sup>9</sup> The primary endpoint was response of ACR20 at week 24.<sup>9</sup>

### **About COSMOS (NCT03796858)**

COSMOS was a Phase 3b, multicentre, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of guselkumab, administered by subcutaneous injection, in 285 adult patients with active PsA and inadequate response to TNFi therapy.<sup>11</sup> The primary endpoint was response of ACR20 at week 24.<sup>11</sup> The primary endpoint results were announced in June 2021.<sup>12</sup> Participants were randomised (2:1) to receive guselkumab 100 mg at weeks 0, 4 and every eight weeks thereafter, or placebo.<sup>11</sup> The study included two periods: a 24-week double-blind, placebo-controlled period for the primary analysis of the efficacy and safety of guselkumab compared with placebo and a 32-week active-treatment and safety follow-up period for additional analysis of the efficacy and safety of guselkumab.<sup>11</sup> Safety was monitored throughout the study to week 56.<sup>11,13</sup> As such, the COSMOS safety results were consistent with the known safety profile of guselkumab in bio-naïve patients with PsA.<sup>8,10,14,15,16</sup>

### **About 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 (a type of inflammation in the fingers and toes that can result in a swollen, sausage-like appearance), axial disease and the skin lesions associated with plaque psoriasis (Pso).<sup>17,18,19</sup> The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 30 and 50, but can develop at any age.<sup>20</sup> Nearly half of patients with PsA experience moderate fatigue and about 30 percent suffer from severe fatigue as measured by the modified fatigue severity scale.<sup>21</sup> In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression are often present.<sup>22</sup> Studies show up to 30 percent of people with plaque Pso also develop PsA.<sup>20</sup> Although the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in disease onset.<sup>23</sup>

### **About TREMFYA® (guselkumab)**

Developed by Janssen, guselkumab is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.<sup>4,24</sup> IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque Pso and active PsA.<sup>24</sup> Guselkumab is approved in the EU for the treatment of moderate to severe plaque Pso in adults who are candidates for systemic therapy, and alone or in combination with methotrexate for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.<sup>4</sup> It is also approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque Pso who are candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.<sup>4,25,26</sup>

*In vitro* studies have demonstrated that guselkumab binds to CD64 expressed on the surface of IL-23 producing cells, and captures IL-23 produced from these same cells when bound to CD64 in an inflammatory monocyte model.<sup>27</sup> The clinical significance of this finding is not known.<sup>28</sup>

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

### **GUSELKUMAB IMPORTANT SAFETY INFORMATION**

In controlled periods of clinical studies with guselkumab, adverse drug reactions (ADRs) that consisted of respiratory tract infections were very common ( $\geq 10$  percent); increased transaminases, headache, diarrhoea, arthralgia, and injection site reactions were common ( $\geq 1$  to  $< 10$  percent); and herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash were uncommon ADRs ( $\geq 0.1$  percent to  $< 1$  percent).<sup>4</sup>

Please refer to the Summary of Product Characteristics for full prescribing information for guselkumab in Pso and PsA: [https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf)

ADRs should be reported. 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. ADRs should also be reported to Janssen-Cilag Ltd. on +44 (0) 1494567447.

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

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### **Cautions Concerning Forward-Looking Statements**

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding guselkumab. 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 Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Scientific Affairs, LLC 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 1, 2023, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in Johnson & Johnson’s subsequent Quarterly Reports on Form 10-Q and other 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 Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Scientific Affairs, LLC 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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