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News Release

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New Data Show Patients Treated with TREMFYA®▼ (guselkumab) Achieve Durable Efficacy Across Joint and Axial Symptoms of Active Psoriatic Arthritis Through Two Years

Adult patients with active psoriatic arthritis experienced persistent multi-domain efficacy and a safety profile consistent with that seen in plaque psoriasis

Further analyses show guselkumab provided sustained improvements across measures of health-related quality of life

BEERSE, BELGIUM, 1 June, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from Phase 3 studies demonstrating patients treated with TREMFYA®▼ (guselkumab) achieved consistent, long-term efficacy through two years across the domains of active psoriatic arthritis (PsA) – including joint, skin, enthesitis,[a] dactylitis,[b] spinal pain and disease severity[c] endpoints – irrespective of baseline characteristics.[1] Further analyses showed

guselkumab also provided patients with sustained improvements in measures of health-related quality of life (HRQoL), including fatigue, pain and work productivity.[2-5] These new data from the DISCOVER-1, DISCOVER-2, and COSMOS studies are among 38 abstracts Janssen is presenting during the 2022 Annual European Congress for Rheumatology (EULAR) meeting taking place virtually and in-person in Copenhagen on June 1-4, 2022.

"Psoriatic arthritis is a complex disease, with a range of joint, skin, and axial symptoms. Patients need long-lasting therapies that can provide efficacy across these varied challenges," said presenting study author Philip Mease, M.D., Swedish Medical Center/Providence St. Joseph Health and University of Washington in Seattle, Washington.[d] "These new data reinforce previous research showing the durable efficacy of guselkumab and demonstrate its effect on health-related quality of life, which is important for patients facing the debilitating effects of psoriatic arthritis in their everyday lives."

The data presented at EULAR show:

Durable Efficacy Across Joint and Axial Symptoms

- Guselkumab-treated patients in DISCOVER-2 achieved consistent, long-term efficacy across domains of active PsA (joint, skin, enthesitis, dactylitis, spinal pain and disease severity endpoints) irrespective of baseline characteristics (POS0072).[1]
    - Further analyses of data from DISCOVER-2 show guselkumab provided continued improvements across the key domains of active PsA recommended by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA;[e] POS1017).[6] In addition, increasing proportions of guselkumab-treated patients with active PsA met minimal disease activity (MDA)[f] criteria through week 100 (POS1067).[7] At week 100, 100 patients or 40 percent of patients treated with guselkumab every eight weeks had achieved MDA, while 59 percent or 147 patients achieved a Disease Activity Index for Psoriatic Arthritis (DAPSA)[g] score

of ≤14, indicating low disease activity, and 24 percent or 60 patients achieved DAPSA ≤4, indicating remission.[6]

- Data from the COSMOS study show complete resolution of dactylitis was achieved in ≥80% of patients who continued to receive guselkumab at week 48 (AB0898).[8] COSMOS investigated patients who had demonstrated inadequate response to tumour necrosis factor inhibition (TNFi-IR), who tend to have more difficult-to-treat manifestations of active PsA.[8]
- Substantial proportions of guselkumab-treated patients in DISCOVER-2 also maintained resolution of dactylitis and enthesitis through two years (POS1028).[9] Among those with the condition at baseline, resolution rates of dactylitis and enthesitis were observed at 64 and 54 percent, respectively, at week 24 among patients treated every 8 weeks (q8w) with guselkumab.[9] These rates increased through week 52 (78 percent and 61 percent, respectively) and were maintained at week 100 (83 percent and 70 percent, respectively among q8w).[9]
- Patients with imaging-confirmed sacroiliitis[h] who received guselkumab maintained improvements in symptoms of axial involvement through two years (POS1037).[10]

Low Rates of Radiographic Progression

- For guselkumab-treated patients in DISCOVER-2, mean changes in radiographic scores indicated low rates of radiographic progression through two years, showing the impact of reducing the progression of structural damage caused by active PsA (POS1035).[11] Radiographic progression is a measure of the structural damage caused by active PsA over time.[12]
- A further analysis showed earlier clinical response to guselkumab predicts low rates of radiographic progression in biologic-naïve active PsA patients (POS1031).[13]

Consistent Safety Profile

- Pooled data from four Phase 2 and Phase 3 clinical trials showed the safety profile for guselkumab was consistent across patients with active PsA who were biologic-naïve and those who were TNFi-experienced (POS1015).[14]
- A further study identified no new safety concerns through two years of guselkumab treatment in active PsA and through five years in plaque psoriasis (Pso), supporting a consistent safety profile across patients with active PsA and moderate to severe plaque Pso (AB0892).[15]

Improvements in Fatigue, Pain, and Work Productivity

- Data from the DISCOVER and VOYAGE-2 studies show patients receiving guselkumab achieved clinically meaningful improvements in fatigue compared with placebo at week 16 in plaque Pso and week 24 in active PsA, as measured by the 36-item Short Form (SF-36) Vitality Scale (AB0893).[16,17]
    - Guselkumab was the first selective IL-23 inhibitor for active PsA to have improvement in fatigue as measured by the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) scale in the product label.[18]
- In addition, analyses of DISCOVER-1 and DISCOVER-2 demonstrated guselkumab provided consistent and durable improvements in pain, with greater improvements relative to placebo (POS1070).[4] Substantial proportions of guselkumab-treated patients reported meaningful improvement in pain at early time points, with 48 percent achieving ≥20 percent improvement at week 8, and 33 percent achieving ≥50 percent improvement at week 16.[4]
- Finally, data from DISCOVER-2 show guselkumab provided patients with active PsA with sustained improvements in self-reported HRQoL[i] and work productivity (WP) through two years (AB0881, AB0888).[2,5] The robust improvements in WP and daily activity seen at week 24 were maintained and increased through this time period.[5]

"We know that the challenging and underestimated symptoms of active psoriatic arthritis can impact patients' ability to perform daily tasks and their overall quality of life," said Terence Rooney, M.D., Ph.D., Vice President, Rheumatology and Maternal

Fetal Disease Area, Janssen Research & Development, LLC. "These robust guselkumab data help us provide more options for patients living with active psoriatic arthritis."

Editor's Notes:

a. Enthesitis is defined as inflammation where tendons and ligaments meet bone. It is associated with certain kinds of arthritis, including active PsA.[19]
b. Dactylitis involves the swelling of fingers or toes and is strongly associated with active PsA.[20]
c. Disease severity was measured through change in the following endpoints: Disease Activity in PsA (DAPSA), swollen joint count (SJC), tender joint count (TJC), Psoriasis Area Severity Index (PASI) score (among patients with baseline Investigator's Global Assessment [IGA] score of ≥2 and body surface area with Pso ≥ 3 percent), Leeds enthesitis index score (among patients with enthesitis at baseline), dactylitis score (among patients with dactylitis at baseline), spinal pain score (among patients with imaging-confirmed sacroiliitis), and Psoriatic Arthritis Disease Activity Score (PASDAS).[1]
d. Dr Mease is a paid consultant for Janssen. He has not been compensated for any media work.
e. GRAPPA guidelines recommend that PsA therapies achieve the lowest possible disease activity across six key domains (peripheral arthritis, skin, dactylitis, enthesitis, axial disease [nails not evaluated]) and related conditions.[6]
f. MDA is defined by fulfillment of 5/7 criteria: TJC ≤1, SJC ≤1, PASI score ≤1, patient pain score ≤15, patient global disease activity score ≤20, Health Assessment Questionnaire–Disability Index (HAQ-DI) score ≤0.5, and ≤1 tender entheses.[7]
g. DAPSA is calculated using TJC and SJC scores, patient's global and pain scores, and the C-reactive protein (CRP) level. A DAPSA score of ≤14 represents a state of low disease activity (DAPSA-LDA), while a score of ≤4 represents remission (DAPSA-REM). Whereas MDA reflects the multifaceted nature of PsA, DAPSA mainly measures articular involvement.[21]
h. Sacroiliitis is inflammation of the joints where the spine and pelvis connect.[22]

i. HRQoL was assessed using the patient-reported EuroQoL-5 Dimension-5 Level (EQ-5D-5L) questionnaire index and EuroQol Visual Analog Scale (EQ-VAS) that allow patients to provide a global assessment of their HRQoL. The EQ-5D-5L index assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-VAS assesses patient health state on a scale of 0-100, with higher scores indicating better health.[2]

About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37)[23,24]

DISCOVER-1 was a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in participants with active PsA, including those previously treated with one or two TNF inhibitors. DISCOVER-1 evaluated 381 participants who were treated and followed through approximately one year.[25] The primary endpoint was response of ACR20 at week 24 and primary endpoint data were previously presented at scientific congresses and published in *The Lancet*.[25] In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70, resolution of soft tissue inflammation, enthesitis and dactylitis, improvement in physical function, skin clearance (IGA), and general health outcomes (36-Item Short-Form Health Survey [SF-36] Physical Component Summary [PCS] and Mental Component Summary [MCS]).[25]

The study consisted of a screening phase of up to six weeks, a blinded treatment phase 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. It also included a safety follow-up phase through week 60 (i.e., approximately 12 weeks from the last administration of study agent at week 48). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.[25]

About DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)[26,27]

DISCOVER-2 is a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in biologic-naïve patients with active PsA. DISCOVER-2 evaluated 739 participants who were treated

and followed through approximately two years. The primary endpoint was response of ACR20 at week 24 and primary endpoint data were previously presented at scientific congresses and published in *The Lancet*.[28] In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70; resolution of soft tissue inflammation, enthesitis and dactylitis; improvement in physical function; skin clearance (IGA); and general health outcomes (SF-36 PCS and MCS). DISCOVER-2 also assessed changes in structural damage as a key secondary endpoint (PsA-modified vdH-S score).[28]

The study consisted of a screening phase of up to six weeks, a blinded treatment phase of 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.[28] 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). Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations were performed in the study on a defined schedule.[28]

About COSMOS (NCT03796858; EudraCT 2018-003214-41)[29,30]

COSMOS was a Phase 3b, multicentre, randomised, double-blind, placebo-controlled study to evaluate the safety and efficacy of guselkumab in 285 patients with active PsA and inadequate response to TNFi therapy. The primary endpoint was ACR20 response at week 24. Participants were randomised (2:1) to receive guselkumab 100 mg at weeks 0, 4 and q8w thereafter, or placebo. 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. Through week 48, non-responder imputation (NRI) rules were used for missing data (after the application of treatment failure rules [TFR]). Safety was monitored throughout the study to week 56.

About Psoriatic Arthritis (PsA)

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 fingers and toes), axial disease, and the skin lesions associated with plaque Pso.[19,20,31] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[32] Studies show up to 30 percent of people with plaque Pso also develop PsA.[33] 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.[33] 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.[34] 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.[35]

About TREMFYA® (guselkumab)[18]

Developed by Janssen, 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.[18] Guselkumab is approved in the EU for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy, and alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[18] 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 may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.[18,36,37,38]

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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 (≥10 percent); increased transaminases, headache, diarrhoea, arthralgia, and injection site reactions were common (≥1 to <10 percent); and herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash were uncommon ADRs (≥0.1 percent to <1 percent).[18]

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

ADRs 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 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) 1494 567447.

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 TREMFYA® (guselkumab) product development. 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 materialise, 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 2, 2022, 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, 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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