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News Release

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New Data Show Majority of Adults with Moderate to Severe Plaque Psoriasis Treated with TREMFYA®▼ (guselkumab) Experienced Durable Skin Clearance Through Five Years Regardless of Metabolic Syndrome Status, Baseline Disease Severity, or Treatment History

Post hoc analysis shows guselkumab responders reported clinically significant improvements across measures of social and sexual function and fatigue

Pooled analysis of seven Phase 2/3 studies of guselkumab in moderate to severe plaque psoriasis shows a consistent safety profile and no new safety signals

BEERSE, BELGIUM, 25 March, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced its interleukin (IL)-23 inhibitor TREMFYA®▼ (guselkumab) provided consistent, durable skin clearance through five years in a majority of adult patients across broad subpopulations with moderate to severe plaque psoriasis (Pso) in the Phase 3 VOYAGE 1 and VOYAGE 2 clinical trials.[1] A separate post hoc analysis of the VOYAGE studies showed guselkumab provided high rates of efficacy and durability through five years and similar safety outcomes among

patients with and without metabolic syndrome status at baseline.[2] These data are among 10 abstracts presented at the 2022 American Academy of Dermatology (AAD) Annual Meeting taking place March 25-29, 2022. 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 (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.[3]

"The latest analyses of VOYAGE 1 and 2 complement the previously reported five-year data from the studies," said Joseph Merola, M.D., M.M.Sc., Associate Professor, Harvard Medical School, Brigham and Women's Hospital.[a] "These additional insights into the potential for guselkumab to mitigate the varied symptoms of psoriasis across broad populations are helpful to physicians as we seek long-term treatment solutions for the many symptoms our patients face with this disease."

For an estimated 125 million people worldwide, plaque Pso can present in varied and debilitating manifestations, including physical and psychological symptoms.[4,5] Plaque Pso can cause inflamed, scaly skin plaques as well as social distress and impairment.[6] The analyses presented at the 2022 AAD Annual Meeting further support the role of guselkumab in improving the symptoms of moderate to severe plaque Pso and outcomes associated with patients' health-related quality of life. These data show:

Durable Skin Clearance in Broad Patient Population

- A pooled analysis of VOYAGE 1 and 2 evaluated the efficacy of guselkumab in 1829 patients across subgroups based on disease severity and treatment history, including an open-label extension period from weeks 52-252. Across the subgroups[b] evaluated, approximately 80 percent of patients achieved and maintained skin clearance as measured by an Investigator's Global Assessment (IGA) Score of 0/1[c] or a Psoriasis Area Severity Index (PASI) 90[d] response.[1]

- IGA 0/1 and PASI 90 responses were evaluated across subgroups defined by patients' baseline PASI and IGA scores, body surface area, and prior Pso treatments.
- Among guselkumab-treated patients, IGA 0/1 or PASI 90 responses were comparable across baseline disease severity characteristics, prior phototherapy, and prior non-biologic systemic therapy. This trend was consistent across subgroups, and the level of efficacy was generally maintained at each timepoint evaluated.[1]

- In a separate post hoc analysis of VOYAGE 1 and 2 data, guselkumab demonstrated high levels of skin clearance, assessed by the achievement of PASI 90, IGA 0/1, and PASI 100 responses among patients with and without metabolic syndrome (MetS).[2,e]
  - Among guselkumab-treated patients, 77.7 percent of patients with MetS (n=256) and 83.4 percent without MetS (n=1118) achieved PASI 90 at week 252.[2]
  - MetS is strongly associated with plaque Pso and should be taken into consideration in treatment decisions.[2,7]
  - These levels of clear or almost clear skin were maintained over time from weeks 100-252 across both groups, in patients with and without MetS.[2]

Reported Improvements in Social and Sexual Function and Fatigue

Guselkumab provided significant clinical improvements for patients across multiple measures of health-related quality of life.

- Results from VOYAGE 1 and 2 show patients with moderate to severe Pso receiving guselkumab reported social relationship difficulty (SRD) and sexual difficulty (SD) measures improved as their skin symptoms improved, based on related questions included in the Dermatology Life Quality Index Questionnaire and PASI scores.[8]
  - At baseline, 35 and 31 percent of patients reported SRD and SD, respectively. At week 16, patients receiving guselkumab or adalimumab

achieved greater improvements in SRD and SD than those receiving placebo.[8]
    - At week 24, the improvements guselkumab-treated patients experienced in SRD and SD were maintained and greater than those for patients receiving adalimumab.[8]
- In addition, two new analyses show greater proportions of patients taking guselkumab versus placebo achieved clinically meaningful improvements in fatigue from baseline across both moderate to severe plaque Pso (at week 16) in the VOYAGE studies and active PsA (at week 24) in the DISCOVER-1 and -2 studies, as measured by the 36-Item Short-Form Health Survey (SF-36)[f] vitality scale.[9,10] These results are important for patients in both disease areas, as people with moderate to severe plaque Pso and active PsA often experience clinically important fatigue, especially in active PsA.[10]

Demonstrated Safety Profile

- Pooled analyses of seven Phase 2/3 studies support the demonstrated safety profile of guselkumab for moderate to severe plaque Pso patients treated for up to five years (2891 patients/8662 patient years).[11] Rates of adverse events (AEs) of interest were shown to be consistent with or numerically lower than those of the general Pso populations in the Psoriasis Longitudinal Assessment and Registry (PSOLAR) and Marketscan database.[11]
    - During the placebo-controlled period, rates of AEs and serious AEs (SAEs) were similar for placebo (341/100 and 6.66/100 patient years) and guselkumab (346/100 and 6.34/100 patient years), respectively. Infection and serious infection rates were similar for placebo (83.61/100 and 1.21/100 patient years) and guselkumab (95.92/100 patient years and 1.06/100 patient years), respectively.[11]
    - Through the end-of-reporting period, these rates remained low for patients treated with guselkumab, as did non-melanoma skin cancer (NMSC; 0.35 per 100 patient years), malignancies other than NMSC (0.43 per 100

patient years), and major adverse cardiac events (0.33 per 100 patient years).[11]
    - Among guselkumab-treated patients, there were no reported cases of active tuberculosis or opportunistic infections and no serum sickness-like/anaphylactic reactions related to guselkumab.[11]
- In the VOYAGE 1 and 2 studies, the safety profile of guselkumab was generally similar in patients with and without MetS at baseline through week 264.[2]

"Despite effective medical treatments for the disease, people living with psoriasis can experience challenges with fatigue, interpersonal relationships, and intimacy," said Lloyd S. Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC.[12,13] "The results of these analyses are encouraging for those living with psoriasis, showing that the long-term improvement of physical symptoms of psoriasis can also be accompanied by improvements to the psychological and social distress associated with the disease."

The latest data are part of Janssen's comprehensive clinical development programme for guselkumab, which includes the recently initiated VISIBLE study, the first large-scale prospective clinical study dedicated to Black, Hispanic, Asian, Indigenous and other people of colour living with moderate to severe plaque Pso.[14-17] Janssen continues to be dedicated to developing therapies that can support patients' unmet needs, including further analyses such as a recent publication in RMD Open that demonstrates the robust and sustained efficacy of guselkumab across domains of active PsA – including skin and joints – in broad subgroups of patients, regardless of baseline characteristics.[18]

Editor's Note:

a. Dr Merola is a paid consultant for Janssen. He has not been compensated for any media work.
b. The number of patients are as follows in each subgroup achieving IGA 0/1 or PASI 90 at week 252, respectively: PASI at baseline <20 n=755 and n=756; PASI at baseline ≥20 n=618 and n=618; IGA score at baseline <4 n=1041

and n=1041; IGA score at baseline=4 n=332 and n=333; BSA at baseline <20% n=544 and n=544; BSA at baseline ≥20% n=829 and n=830; never used prior treatment of phototherapy at baseline n=581 and n=581; used phototherapy prior treatment at baseline n=791 and n=792; never used prior treatments of non-biologic systematic therapies at baseline n=458 and n=458; used prior treatments of non-biologic systematic therapies at baseline n=915 and n=916; never used prior treatments of biologics at baseline n=1103 and n=1104 and used prior treatments of biologics at baseline n=270 and n=270.[1]

c. The IGA Score is a 5-point clinical scale evaluating disease severity.[19] IGA 0 and 1 are defined as clear and almost clear skin, respectively.
d. PASI 90 is defined as at least 90 percent improvement from baseline in the PASI score. The PASI score grades the amount of surface area on each body region that is covered by Pso plaques and the severity of plaques for their redness, thickness, and scaliness.[20]
e. MetS was defined in this study as ≥3 of the following: body mass index >30 kg/m;[2] triglycerides ≥150 mg/dL; HDL cholesterol <40/<50 mg/dL (men/women); blood pressure ≥130/85 mmHg; and fasting glucose ≥110 mg/dL.[2]
f. SF-36 is a set of quality-of-life measures used for patient self-reporting. The SF-36 includes one multi-item scale that assesses eight health concepts: limitations in physical activities because of health problems; limitations in social activities because of physical or emotional problems; limitations in usual role activities because of physical health problems; bodily pain; general mental health (psychological distress and well-being); limitations in usual role activities because of emotional problems; vitality (energy and fatigue); and general health perceptions.[21]

About VOYAGE 1 (NCT02207231; EudraCT 2014-000719-15)[14,22,23]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial with 837 patients was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque

Pso. Patients were randomised to receive placebo at weeks 0, 4 and 12, followed by crossover to guselkumab at weeks 16 and 20 and then every eight weeks (q8w) dosing; guselkumab 100 mg at weeks 0, 4 and 12, followed by q8w dosing; or adalimumab 80 mg (n= 334) at week 0, followed by 40 mg at week 1, then dosing every two weeks (q2w) through week 47, with crossover to guselkumab q8w at week 52.

The co-primary endpoints of the study were the proportions of patients receiving guselkumab versus patients receiving placebo achieving IGA 0/1 (clear/almost clear skin) and PASI 90 at week 16. Secondary endpoints were assessed at weeks 16, 24, and 48, with safety monitoring throughout the study. Through week 48, non-responder imputation (NRI) rules were used for missing data (after the application of treatment failure rules [TFR]).

During the open-label extension period, which started at week 52, all patients continued open-label treatment with guselkumab through week 252. Efficacy assessments included proportions of patients achieving PASI 90, PASI 100, IGA 0/1, and IGA 0 (clear skin). Efficacy was analysed using pre-specified TFR for the primary analysis, while NRI and as observed (OBS) methodology were used for the secondary analyses.

About VOYAGE 2 (NCT02207244; EudraCT 2014-000720-18)[24,25]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque Pso. Patients (N=992) were randomised to receive subcutaneous (SC) injections of guselkumab 100 mg (n=496) at weeks 0, 4 and q8w thereafter; placebo (n=248) at weeks 0, 4, and 12 followed by crossover to guselkumab 100 mg at week 16; or adalimumab 80 mg (n=248) at week 0, 40 mg at week 1, then 40 mg q2w until week 23. Weeks 28-72 incorporated a randomised withdrawal study design. During the open-label period (weeks 76-252), all patients received guselkumab 100 mg q8w. Physician- and patient-reported outcomes were assessed. Efficacy was analysed using pre-specified

treatment failure rules (patients discontinuing due to lack of efficacy, worsening of Pso, or use of a prohibited treatment were considered non-responders). Data were combined for patients randomised to guselkumab and for those originally randomised to placebo who later crossed over to guselkumab at week 16. Patients were treated and followed for up to 264 weeks.

Co-primary endpoints of the study were proportions of patients receiving guselkumab versus patients receiving placebo achieving IGA 0/1 (clear/almost clear) [84 percent versus 9 percent, respectively; $p<0.001$ versus placebo] and PASI 90 [70 percent versus 2 percent, respectively; $p<0.001$ versus placebo] at week 16. Additional efficacy assessments included proportions of patients achieving PASI 75, and PASI 100 responses, as well as IGA scores of 0, a Dermatology Life Quality Index (DLQI) score of 0/1, a Psoriasis Signs and Symptoms Diary (PSSD) score of 0, SF-36, the Hospital Anxiety and Depression Scale (HADs), and the Work Limitations Questionnaire (WLQ). Efficacy was analysed using pre-specified treatment failure rules, non-responder imputation, and as observed methodology.

About Plaque Psoriasis (Pso)

Plaque Pso is an immune-mediated disease resulting in an overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[4] It is estimated that more than 125 million people worldwide live with the disease.[5] Nearly one-quarter of all people with plaque Pso have cases that are considered moderate to severe.[5] Living with plaque Pso can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[6]

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.[26-29] In addition, in patients with PsA, comorbidities, such as obesity, cardiovascular diseases, anxiety and depression are

often present.[29] Studies show up to 30 percent of people with plaque Pso also develop PsA.[30] 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.[30] 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.[31] 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.[32]

About TREMFYA® (guselkumab)

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.[3] Guselkumab is approved in the EU for the treatment of moderate to severe plaque psoriasis (Pso) 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.[3] 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.[3]

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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).[3]

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

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.

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Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU, and Janssen Research & Development, LLC are each 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 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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