JANSSEN’S TREMFYA® IMPROVES LONG-TERM PATIENT-REPORTED OUTCOMES IN PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

- New data show marked improvements in long-term patient-reported outcomes in patients switched to guselkumab after an inadequate response to initial treatment with adalimumab
- Patient-reported symptom-free status shown to be a better indicator of quality of life improvement than The Psoriasis Area and Severity Index (PASI) 100 response

Paris, France, 13:30 CEST, 12 September, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson has announced new data that show considerable improvements in long-term patient-reported outcomes (PRO) in patients switched to TREMFYA® (guselkumab) after an initial inadequate response to adalimumab.¹ In addition, PRO measurement tools such as the Psoriasis Symptom and Sign Diary (PSSD) may provide a more accurate representation of the impact of psoriasis on the patient in comparison to current clinical measurement tools.² These long-term findings from the Phase III VOYAGE 1 & 2 clinical trial programme are part of six abstracts Janssen presented today at the European Academy of Dermatology and Venereology (EADV) 2018 Congress in Paris, France.

Dr Jaime Oliver, Medical Lead for Immunology in EMEA, Janssen Biologics B.V. said: "The data presented at EADV highlights Janssen’s commitment to developing effective treatments that translate into real-term positive outcomes for patients. This long-term data not only demonstrates the potential for guselkumab to improve psoriasis signs and symptoms which matter most to patients, but also shows the significance of PRO measurement tools when it comes to improving the quality of life for patients living with this debilitating condition."

Study findings showed a switch to guselkumab at Week 28, after an inadequate response to Humira® (adalimumab), led to a sustained improvement in patient reported outcomes in both the PSSD and DLQI (Dermatology Life Quality Index) score at Week 100.¹ The proportion of patients with a PSSD score of 0, i.e. no impact of psoriasis on quality of life, increased from 4.2% and 1.1% at Week 28, to 32.6% and 18.0% at Week 100, for symptoms and signs respectively. The proportion of patients with a DLQI score of 0 to 1 (i.e. no impact on patient quality of life) increased from 14.4% at Week 28 to 65.3% at Week 100, showing that guselkumab is consistently able to positively impact patient well-being.

Further data presented at EADV 2018 demonstrated that PRO tools are redefining treatment goals from the patient’s perspective. A symptom-free status on PSSD was shown to be associated with greater improvements in health-related quality of life (HRQoL) than a PASI 100 response for patients with moderate to severe psoriasis.² While clinician-determined PASI assessments and patient-reported PSSD outcomes were highly correlated, there were discrepancies between PASI

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² Further data presented at EADV 2018 demonstrated that PRO tools are redefining treatment goals from the patient’s perspective. A symptom-free status on PSSD was shown to be associated with greater improvements in health-related quality of life (HRQoL) than a PASI 100 response for patients with moderate to severe psoriasis. While clinician-determined PASI assessments and patient-reported PSSD outcomes were highly correlated, there were discrepancies between PASI
100 response rates and patient-assessed achievement of symptom- and sign-free status. In addition, data showed that, in comparison to the PASI 100 response rate, patient-reported outcomes from the PSSD were more aligned to the DLQI score. These findings emphasise the importance of using PRO measurement tools, such as the PSSD, as an additional tool to assess the true impact of psoriasis on patients, and to determine an accurate response to therapy.

During clinical development, guselkumab was generally tolerated by patients with psoriasis. The very common and common adverse events associated with guselkumab are as follows: upper respiratory infection (very common, ≥ 1/10) and arthralgia, diarrhoea, gastroenteritis, headache, herpes simplex infections, injection site erythema, tinea infections and urticaria (common, ≥ 1/100 to < 1/10). Injection site pain has been reported as an uncommon adverse event (≥ 1/1,000 to < 1/100). In the clinical studies, the types of adverse events reported remained generally consistent through 100 weeks of treatment.

Information for Editors

Clinical measurement tools
The negative impact of psoriasis on people’s lives can be immense, which is why the measurement of health-related quality of life (HRQoL) is now a major component of the assessment of psoriasis.

The Dermatology Life Quality Index (DLQI) is a 10-item questionnaire that assesses disease-related impact on quality of life, including daily activities, work and personal relationships. The score per question ranges from 0 (not at all) to 3 (very much) and total scores range from 0 to 30, with scores >10 indicating a ‘moderate’ to ‘extremely large’ negative impact on QoL.

The Psoriasis Area and Severity Index (PASI) is a physician assessment tool for defining disease severity based on the visible signs of lesions and affected areas. Most trials for psoriasis currently use PASI 75 (75% clearing of skin lesions) as a primary endpoint.

While the DLQI has been the most widely used validated measure for assessing quality of life in psoriasis trials it is not psoriasis specific and the PASI, a physician assessment tool for defining disease severity, is only based on the visible signs of lesions and affected areas.

The PSSD covers all major patient-reported symptoms and signs and is the most comprehensive PRO instrument currently available. The PSSD includes 11 items covering 5 patient-reported symptoms (itch, pain, stinging, burning, skin tightness) and 6 visible signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using a numerical rating scale ranging from 0–10 (higher score indicating more severe psoriasis). The total PSSD score includes all 11 individual items (both symptom and signs) and average value of all 11 items is converted into a 0–100 score, where 0=least severe to 100=most severe.

About Psoriasis

What it is
The most common form of psoriasis is plaque psoriasis, usually resulting in areas of thick, red or inflamed skin covered with silvery scales which are known as plaques. The inconsistent nature of psoriasis means that even when plaques appear to subside, patients can have ongoing concerns over their return.
**Impact**
Psoriasis can cause great physical and psychological burden. Mental health issues are common among people with psoriasis, and the impact it can have on quality of life is comparable with diabetes and cancer.\(^{14}\) Psoriasis is also associated with several comorbidities including psoriatic arthritis, cardiovascular diseases, metabolic syndrome, chronic obstructive pulmonary disorder (COPD) and osteoporosis.\(^{15}\) In addition, many individuals are faced with social exclusion, discrimination and stigma because of their disease.\(^{16}\)

**Congress information**
The European Academy of Dermatology and Venereology (EADV) congress is taking place in Paris, France from Wednesday 12\(^{\text{th}}\) September to Sunday 16\(^{\text{th}}\) September. For more information visit: [https://eadvparis2018.org/](https://eadvparis2018.org/).

**About TREMFYA® (guselkumab)\(^7\)**
On 10 November 2017, TREMFYA® (guselkumab) was granted market authorisation in the European Union for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy).\(^7\)

Guselkumab is the first psoriasis treatment licensed in the European Union to selectively target IL-23, a key driver of the immune inflammatory response in psoriasis.\(^4\),\(^5\),\(^6\),\(^17\) Guselkumab is a subcutaneous, self-injectable treatment for psoriasis (following training). Treatment requires two starter doses, one initially and the other four weeks later, followed by a maintenance dose once every eight weeks (q8w) thereafter.\(^4\),\(^5\),\(^18\)

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to guselkumab, which is currently approved in the US, Canada and the European Union.

**VOYAGE 1, VOYAGE 2 and NAVIGATE studies**
- **VOYAGE 1** is a Phase III, multicentre, randomised, double-blind, placebo- and active comparator-controlled study, including 837 patients. It included a placebo-controlled period (Weeks 0–16), after which patients taking placebo crossed over to receive guselkumab through Week 48, and an active comparator-controlled period comparing guselkumab with adalimumab (Week 0–48).\(^4\) Patients randomised to guselkumab at Week 0 and those who crossed over from placebo to guselkumab at Week 16 continued to receive guselkumab q8w at Week 48.\(^4\) Beginning at Week 52, all patients began receiving open-label guselkumab. This study will continue for a total of 5 years.

- **VOYAGE 2** is a Phase III, multicentre, randomised, double-blind, placebo- and active comparator-controlled study, including 992 patients. It consisted of a placebo-controlled period (Weeks 0–16), an active comparator-controlled period (Weeks 0–28), and a randomised withdrawal and retreatment period (Weeks 28–72).\(^5\) Beginning at Week 76, all patients began receiving open-label guselkumab. This study will continue for a total of 5 years.

- A third phase III study was included as part of the regulatory submission, the NAVIGATE study. NAVIGATE was a Phase III, multicentre, randomised, double-blind study, including 871 patients. All patients received open-label ustekinumab treatment (patients weighing $\leq 100$ kg: 45 mg, patients weighing $> 100$ kg: 90 mg) at Weeks 0 and 4. At Week 16,
patients with an inadequate response to ustekinumab (IGA score ≥ 2) were randomised in a double-blinded fashion to receive guselkumab at Weeks 16, 20, and every 8 weeks thereafter through Week 44, or to continue ustekinumab at Week 16 and every 12 weeks thereafter through Week 40. The final safety follow-up visit was at Week 60.6

Prescribing and safety information

For complete European Union (EU) prescribing and safety information, please visit: https://www.medicines.org.uk/emc/medicine/34321

▼ Adverse events should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events 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. Adverse events should also be reported to Janssen-Cilag Ltd on 01494 567447.

Clinical development programme

Phase III studies are being undertaken to evaluate the efficacy and safety of guselkumab for patients with psoriatic arthritis and Crohn’s disease.19,20 A Phase III comparator study (the ECLIPSE study) is underway to evaluate the efficacy of guselkumab versus Cosentyx® (secukinumab), an IL-17A inhibitor, in patients with moderate to severe plaque psoriasis.18

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/EMEA. Follow us on Twitter: @JanssenEMEA. Janssen Biologics B.V. is 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 development and potential availability in the European Union of 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 materialise, actual results could vary materially from the expectations and projections of Janssen Biologics B.V., Janssen-Cilag Ltd or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 December 31, 2017, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in the company’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.

References