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New Phase 3 data demonstrate superiority of TREMFYA®▼ (guselkumab) vs Cosentyx® (secukinumab) in delivering PASI 90 responses in the treatment of moderate to severe plaque psoriasis at week 48

- *84.5 percent of patients receiving TREMFYA® (guselkumab) achieved the primary endpoint of a PASI 90 response at week 48 compared with 70.0 percent of patients receiving Cosentyx® (secukinumab)*
- *ECLIPSE is the first Phase 3 head-to-head study to compare efficacy between first-in-class IL-23 inhibitor, guselkumab, and the IL-17 inhibitor, secukinumab*

VIENNA, AUSTRIA, Wednesday 12 December, 2018 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the ECLIPSE study demonstrating that TREMFYA® (guselkumab) was superior to Cosentyx® (secukinumab)* in treating adults with moderate to severe plaque psoriasis for the primary endpoint assessed at week 48. Data from the multicentre, randomised, double-blind head-to-head Phase 3 study demonstrated that 84.5 percent of patients treated with guselkumab achieved at least 90 percent improvement in their baseline Psoriasis Area Severity Index (PASI) score at week 48, compared with 70.0 percent of patients treated with secukinumab ($p<0.001$).[1]

These data, presented at the 3rd Inflammatory Skin Disease Summit (ISDS) in Vienna, 12–15 December, mark the first-ever results from a head-to-head study comparing an interleukin (IL)-23-targeted biologic therapy (guselkumab) with an IL-17 inhibitor (secukinumab). ECLIPSE is Janssen's fourth Phase 3 study for guselkumab in plaque psoriasis[2-4] and is part of a comprehensive clinical development programme that also includes ongoing Phase 3 studies in psoriatic arthritis and Crohn's disease.[5,6]

"Psoriasis is a painful, debilitating and life-long condition, and those who suffer from it are in need of treatments that not only work well, but work well for a long time," said Dr Jaime Oliver, MD, Janssen Therapeutic Area Lead, Immunology, Europe, Middle East & Africa, Cilag GmbH International. *"The evidence supporting guselkumab shows that not only does this treatment offer patients high levels of skin clearance, but our current 3-year data shows a consistent maintenance of efficacy – something we hope to see continue as we gain more data."*

ECLIPSE incorporated six major secondary endpoints that used a fixed statistical sequence procedure to control for multiple comparisons and included both shorter and longer-term analyses. Guselkumab demonstrated non-inferiority to secukinumab in the first major secondary endpoint, with 84.6 percent of patients on guselkumab achieving a PASI 75 response at both weeks 12 and 48 versus 80.2 percent of those on secukinumab ($p<0.001$), however, it did not demonstrate superiority ($p=0.062$). Because superiority was not demonstrated for the first major secondary endpoint, p-values for all the subsequent major secondary endpoints were considered nominal.[1]

Three of the remaining major secondary endpoints evaluated efficacy at week 48, including achievement of a PASI 100 response and Investigator's Global Assessment (IGA) scores of 0 (cleared), or 0 or 1 (cleared or minimal disease). At week 48, 58.2 percent of patients receiving guselkumab achieved a PASI 100 response, compared with 48.4 percent of patients receiving secukinumab; 62.2 percent of patients receiving guselkumab achieved an IGA score of 0 compared to 50.4 percent of patients receiving secukinumab and 85.0 percent of patients receiving guselkumab achieved an IGA score of 0 or 1 compared to 74.9 percent of patients receiving secukinumab (all comparisons with nominal $p\leq0.001$).[1]

The remaining major secondary endpoints assessed non-inferiority of guselkumab versus secukinumab at week 12. The percentage of patients achieving a PASI 75 response at week 12 was 89.3 percent for guselkumab and 91.6 percent for secukinumab ($p<0.001$ for non-inferiority); the percentage of patients achieving a PASI 90 response at week 12 was 69.1 percent for guselkumab and 76.1 percent for secukinumab ($p=0.127$ for non-inferiority).[1]

"The response-over-time curves show that maximum response rates with guselkumab are achieved after six months and are maintained over time through one year, achieving superiority at the primary endpoint of the study," said lead study investigator Richard Langley†, M.D., FRCPC, Professor, Division of Clinical Dermatology & Cutaneous Science, Department of Medicine, Dalhousie University, Canada. *"Results of the study confirm a slightly more rapid onset of response with secukinumab, but importantly in a chronic disease like psoriasis, these data provide new insights into comparative longer-term efficacy."*

The safety profiles observed for guselkumab and secukinumab in ECLIPSE were consistent with the known safety profiles seen in the respective registration trials and current prescribing information. Similar percentages of patients receiving guselkumab (77.9 percent), and secukinumab (81.6 percent) reported at least one adverse event (AE). Serious AEs were reported in 6.2 percent of patients receiving guselkumab and 7.2 percent of patients receiving secukinumab. Serious infections occurred in six patients receiving guselkumab and five patients receiving secukinumab.[1]

"*Fortunately for patients, there are many good treatment options available for plaque psoriasis today. However, to make the best recommendation for their patients from among these options, physicians need long term comparative safety and efficacy data. We're proud to have conducted this important trial to help guide clinical practice and continue to build on the robust database of clinical information that we've been able to generate on guselkumab, the first IL-23 inhibitor*," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC.

#ENDS#

*__Cosentyx__ (secukinumab) is a trademark of Novartis AG.

†*Dr Langley is a paid consultant for Janssen. He was not compensated for any media work.*

Information for Editors

About ECLIPSE

The Phase 3, multicentre, randomised, double-blind, active comparator trial, ECLIPSE, was designed to evaluate the efficacy and safety of guselkumab compared with secukinumab in adult patients with moderate to severe plaque psoriasis. Patients (n=1048) were randomised to receive 100 mg of guselkumab administered by subcutaneous (SC) injection at weeks 0 and 4, followed by a maintenance dose every 8 weeks; or 300 mg of secukinumab administered by two SC injections of 150 mg at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. The primary endpoint of the study was the proportion of patients achieving a PASI 90 response at week 48. Secondary endpoints were assessed at weeks 12 and 48, with safety monitoring through week 56.[1]

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.[7] The inconsistent nature

of psoriasis means that even when plaques appear to subside, patients can have ongoing concerns over their return.[8]

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.[9] Psoriasis is also associated with several comorbidities including psoriatic arthritis, cardiovascular diseases, metabolic syndrome, chronic obstructive pulmonary disorder (COPD) and osteoporosis.[10] In addition, many individuals are faced with social exclusion, discrimination and stigma because of their disease.[11]

About TREMFYA® (guselkumab)[12]

On 10 November 2017, 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).[12]

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.[2-4,13] 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 thereafter.[2,3,14]

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

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.

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-Cilag International NV, the marketing authorisation holder for TREMFYA® in the European Union, Janssen-Cilag Ltd, and Janssen Research & Development, LLC, are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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