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ASIA EDITION

U.S. FDA approves Janssen's TREMFYA for the treatment of moderate to severe plaque psoriasis

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TREMFYA (guselkumab) demonstrated superior results in skin clearance compared with Humira (adalimumab) in head-to-head analyses at weeks 16, 24 and 48.

Janssen Biotech, Inc. has announced that the U.S. Food and Drug Administration (FDA) approved TREMFYA (guselkumab) for the treatment of adults living with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

According to a press release, TREMFYA is the first and only approved biologic therapy that selectively blocks only IL-23, a cytokine that plays a key role in plaque psoriasis. Approval comes after an expedited regulatory review following application of an FDA Priority Review Voucher. TREMFYA is administered as a 100 mg subcutaneous injection every eight weeks, following two starter doses at weeks 0 and 4. In clinical studies, patients receiving TREMFYA experienced significant improvement in skin clearance and greater improvement in symptoms of plaque psoriasis including itch, pain, stinging, burning and skin tightness when compared with placebo at week 16. Superior results in skin clearance (PASI 90) were demonstrated with TREMFYA compared with Humira (adalimumab) at weeks 16, 24 and 48.

"TREMFYA represents a significant milestone in the treatment of moderate to severe plaque psoriasis as evidenced by the proven skin clearance demonstrated in the majority of study patients receiving this IL-23–specific therapy at week 16 and up to week 48," said Andrew Blauvelt, M.D., M.B.A., President of Oregon Medical Research Center, and study investigator. "We continue to make progress in understanding the science of psoriasis and the important role IL-23 plays in the pathogenesis of this disease, which is another reason why today's approval of TREMFYA is exciting, both as a researcher and a practicing dermatologist."

"Living with plaque psoriasis is challenging, especially the constant pain, itching and burning," said Patti Janick, a guselkumab clinical trial participant. "I am encouraged by the results I've experienced with TREMFYA and the possibility it offers others living with plaque psoriasis to find similar relief and clearer skin."

TREMFYA received FDA approval based on results from a clinical development program that included more than 2,000 patients in the Phase 3 VOYAGE 1, VOYAGE 2 and NAVIGATE studies, which have been published in peer-reviewed journals and were presented at the 25th European Academy of Dermatology and Venerology Congress and the 2017 American Academy of Dermatology Annual Meeting.

“Addressing the need for additional safe and effective plaque psoriasis therapies has been a critical area of focus at Janssen for more than 15 years,” said Andrew Greenspan, M.D., Vice President of Medical Affairs at Janssen. “Considering this, we applied a priority review voucher to the application for TREMFYA to bring this novel treatment to patients sooner.”

“The approval of new and effective treatment options is always welcome news for the plaque psoriasis patient community, as not all patients respond similarly to currently available treatments,” said Michael Siegel, Ph.D., Vice President of Research Programs for the National Psoriasis Foundation. “For the more than one million Americans living with moderate to severe plaque psoriasis, the approval of TREMFYA is a meaningful addition and offers physicians and patients an effective new, first-in-class therapy that selectively inhibits IL-23.”

Janssen will work closely with payers, providers and pharmacy benefit managers to ensure TREMFYA is broadly accessible and affordable for patients and that the cost for payers is competitive with currently available biologic therapies for psoriasis. Janssen offers a number of patient support programs, including a co-pay card for patients with commercial insurance that reduces their out-of-pocket cost for TREMFYA to no more than $5 per dose.

About TREMFYA (guselkumab):

TREMFYA is a human monoclonal antibody developed by Janssen that selectively blocks the protein interleukin (IL)-23 and is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light). A Phase 3 study evaluating TREMFYA in the treatment of active psoriatic arthritis is ongoing, and a Phase 3 program evaluating the efficacy of TREMFYA compared with Cosentyx (secukinumab) in the treatment of moderate to severe plaque psoriasis is underway.

Applications seeking approval in the European Union, Japan and other countries are currently under review.