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FDA Approves TREMFYA Label Expansion for Structural Joint Damage in Psoriatic Arthritis

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The label update positions TREMFYA as the only IL-23 inhibitor in the US with evidence for inhibiting progression of structural joint damage in active psoriatic arthritis.

Johnson & Johnson has received US FDA approval for a supplemental Biologics License Application to include evidence in the TREMFYA label for inhibition of progression of structural joint damage in adults with active psoriatic arthritis.

The update addresses an important treatment goal in psoriatic arthritis: preventing irreversible joint damage while managing symptoms. Joint damage can develop early in the disease course, affecting mobility, work productivity and quality of life.

TREMFYA, or guselkumab, is an IL-23 inhibitor approved across several immune-mediated indications. The label expansion differentiates it within the IL-23 class by including evidence that it can help inhibit further structural joint damage in active psoriatic arthritis.

The update is supported by 24-week results from the Phase 3b APEX study. The trial met its primary endpoint of reducing joint symptoms, measured by ACR20, and its major secondary endpoint of inhibiting progression of structural damage compared with placebo in biologic-naïve patients.

For patients in the placebo group who switched to TREMFYA at Week 24, the rate of radiographic progression was reduced by 57 percent from Week 24 through Week 48. The data were consistent with the established safety profile of TREMFYA, with no new safety signals identified.