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Novartis Gets FDA Approval for Cosentyx Label Update

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The updated label includes Cosentyx data in moderate-to-severe scalp psoriasis

Novartis announced that the US Food and Drug Administration (FDA) has approved a label update for Cosentyx® (secukinumab), the first interleukin-17A (IL-17A) antagonist approved to treat moderate to severe plaque psoriasis.

The updated label includes Cosentyx data in moderate to severe scalp psoriasis; one of the difficult-to-treat forms of the disease, which affects approximately half of all psoriasis patients.

The label update is effective in the US immediately, and is based on the proven efficacy and consistent safety profile of Cosentyx from a dedicated Phase III scalp psoriasis trial.

The updated label for Cosentyx in scalp psoriasis addresses an important unmet need. Scalp psoriasis can be challenging to treat with topical agents or phototherapy due to the presence of hair and other factors.

Cosentyx is currently the only fully human IL-17A antagonist to demonstrate efficacy and safety in a dedicated Phase IIIb study of scalp psoriasis.

The label update is based on 12-week primary endpoint results from the US study of moderate to severe scalp psoriasis patients where Cosentyx (300 mg) demonstrated superior efficacy compared to placebo.

Cosentyx, in a separate study, has demonstrated sustained long-term efficacy, as well as a safety profile consistent with that seen in pivotal trials.