US FDA approves J&J's oral psoriasis pill

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Bengaluru: The U.S. Food and Drug Administration has approved Johnson & Johnson's oral pill for psoriasis, the company said on Wednesday, paving the way for a more convenient treatment option for patients with the chronic autoimmune condition that causes itchy, scaly, and inflamed patches of skin.

The drug will help J&J expand into the psoriasis market, as its blockbuster injectable Stelara comes under increasing competition from low-cost copycat drugs.

The health regulator approved the drug for moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg.

The company did not immediately respond to Reuters' requests for comment on pricing and availability.

The drug, branded as Icotyde, will compete with Bristol Myers Squibb's Sotyktu and AbbVie's Skyrizi.

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The drug has shown superior skin clearance compared to Bristol's Sotyktu, in two late-stage head-to-head trials.

Patients have been looking for complete skin clearance, a favorable safety profile, and the simplicity of a once-a-day pill, David Lee, J&J's global head of immunology, told Reuters ahead of the decision. "We see Icotyde as becoming the first-line systemic therapy for psoriasis patients," said Lee.

J&J's oral pill, like AbbVie's Skyrizi and J&J's own Tremfya, is designed to block a protein, IL-23, involved in inflammatory responses. The oral drug is developed in partnership with Protagonist Therapeutics.

J&J is also studying the drug, chemically known as icotrokinra, for ulcerative colitis, psoriatic arthritis and Crohn's disease.

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