FDA approves Wezlana for multiple inflammatory diseases

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The U.S. Food and Drug Administration has approved Amgen's Wezlana (ustekinumab-auub) as a biosimilar to and interchangeable with Stelara (ustekinumab) for multiple inflammatory diseases.

The approval includes indications for adults with moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn disease, and moderately to severely active ulcerative colitis. Additionally, the approval includes indications for pediatric patients (aged six years and older) with moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy and those with active psoriatic arthritis.

Approval of Wezlana was based on a review of scientific evidence that showed it is highly similar to Stelara in terms of safety, purity, and potency. E

vidence from chemical and biological tests and biological assays confirmed similarity in the structural and functional features of Wezlana and Stelara (including those known to impact safety and efficacy). Additionally, evidence included comparative human pharmacokinetic data, clinical immunogenicity data, and other clinical safety and effectiveness data. Infection is the most serious known side effect in both drugs.

"Biosimilar medications offer additional safe and effective treatment options that have the potential to increase access for people requiring treatment for inflammatory diseases," Nikolay Nikolov, M.D., from the FDA Center for Drug Evaluation and Research, said in a statement. "Today's approval could have a meaningful impact for patients managing their disease."

More information: More Information