FDA expands pediatric indication for Rinvoq

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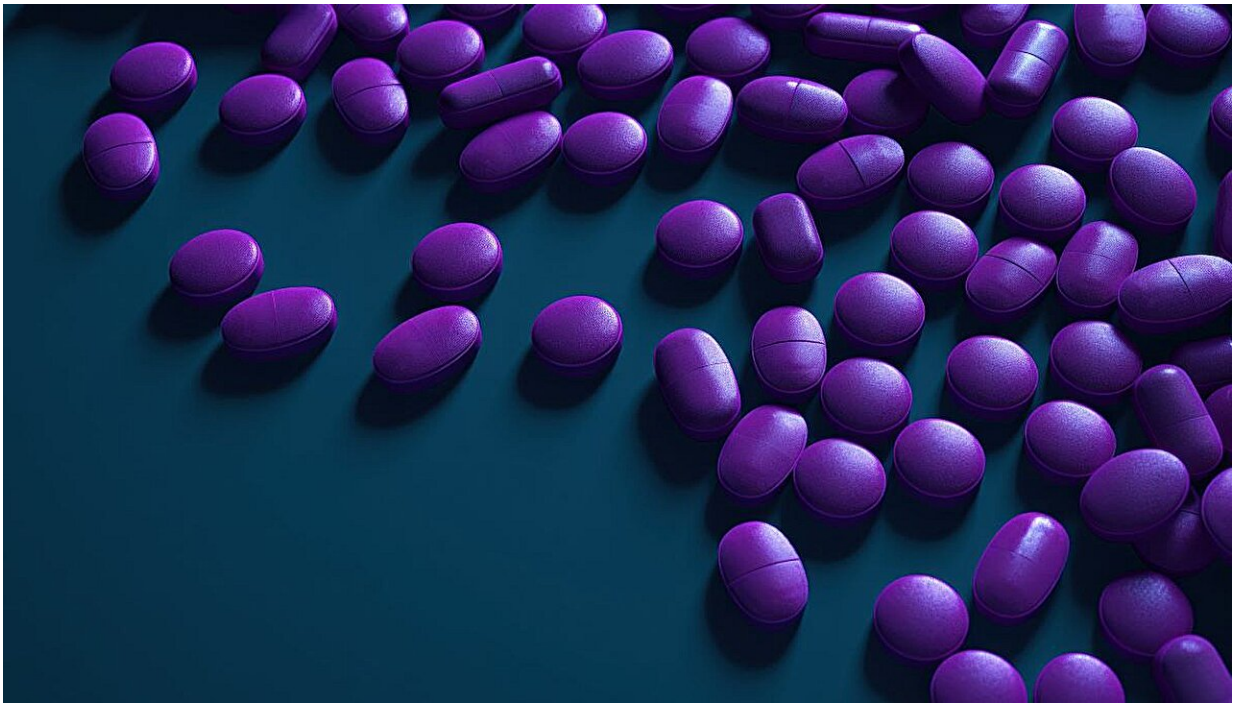

The U.S. Food and Drug Administration has expanded indications for AbbVie's Rinvoq (upadacitinib) to now include pediatric patients (ages 2 years and older) with polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA).

Rinvoq is indicated for pediatric patients with an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. In

addition, Rinvoq LQ, a new weight-based oral solution, is available for these pediatric patients.

The expanded indication is based on pharmacokinetic data from 51 patients with pJIA with active polyarthritis and safety data from 83 patients with pJIA with active polyarthritis. At the recommended doses, upadacitinib plasma exposures in pediatric patients with pJIA and PsA are expected to be comparable to those observed in adults with rheumatoid arthritis and PsA based on population pharmacokinetic modeling and simulation.

"Pediatric patients with pJIA and PsA can be severely limited in their ability to complete daily physical tasks and participate in everyday activities. Understanding their needs today and knowing the likelihood of disease in adulthood underscores the need for additional treatment options," Aarat Patel, M.D., from the Bon Secours Rheumatology Center of St. Mary's Hospital in Richmond, Virginia, said in a statement.

"Having a treatment option available for patients who do not respond well to a TNF inhibitor addresses a need for the health care community, patients, and their families."

More information: More Information