Simponi Aria® (golimumab) – New indication, expanded indication

- On September 30, 2020, Janssen announced the FDA approval of Simponi Aria (golimumab), for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.
- In addition, Janssen announced the approval of Simponi Aria for treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.
    - Simponi Aria was previously approved for this indication in adult patients.
- Simponi Aria is also approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) and adult patients with active ankylosing spondylitis.
- The approval of Simponi Aria in pediatric patients with pJIA was based on the pharmacokinetic exposure and extrapolation of the established efficacy of Simponi Aria in RA patients. Efficacy of Simponi Aria was also assessed in an open-label, single-arm study in 127 children with JIA with active polyarthritis. The efficacy of Simponi Aria was generally consistent with responses in patients with RA.
- The approval of Simponi Aria for pediatric patients with PsA was based on the pharmacokinetic exposure and extrapolation of the established efficacy of Simponi Aria in adult PsA patients.
- Simponi Aria carries a boxed warning for serious infections and malignancy.
- The recommended dose of Simponi Aria for the treatment of pediatric patients with pJIA and PsA is 80 mg/m^2 given as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter.
- Refer to the Simponi Aria drug label for dosing in adults and for its other indications.

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