FDA adds Fasenra indication for severe asthma in children

April 17 2024, by Lori Solomon

The U.S. Food and Drug Administration has approved an additional indication for AstraZeneca's Fasenra (benralizumab) as an add-on maintenance treatment for patients aged 6 to 11 years with severe asthma and an eosinophilic phenotype.

This indication was supported by evidence from the Phase III TATE trial, as well as data from additional well-controlled trials in adult and adolescent populations. Results among children aged 6 to 11 years old show that Fasenra met the primary end points, demonstrating pharmacokinetics and pharmacodynamics with severe eosinophilic asthma. The safety and tolerability results were also consistent with the known profile.

The recommended dose for Fasenra is 30 mg for patients ages 6 years and older who weigh ≥35 kg, while a new 10-mg dose will be available for patients aged 6 to 11 years who weigh