

**FDA rejects benralizumab application for chronic rhinosinusitis  
with nasal polyps**

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AstraZeneca has received an FDA complete response letter concerning its supplemental biologics license application for benralizumab for the treatment of inadequately controlled chronic rhinosinusitis with nasal polyps.

The FDA asked for additional clinical data in the response letter.

The application included data from the phase 3 OSTRO trial, which met both of its co-primary endpoints with a safety profile consistent with the known profile of benralizumab (Fasenra), a humanized, afucosylated monoclonal antibody that binds to cells that express the IL-5 receptor. Changes from baseline to week 40 in nasal polyp score (NPS) and patient-reported biweekly mean nasal blockage score (NBS) served as the co-primary endpoints.

Patients assigned benralizumab reported significant improvements in their NPS (between-group difference,  $-0.57$ ; 95% CI, 0.852-0.289) and NBS (between-group difference,  $-0.27$ ; 95% CI,  $-0.458$  to  $-0.083$ ) at week 40 compared with those assigned placebo.

But there were no statistically significant improvements in Sinonasal Outcome Test-22 scores at week 40 (least-squares mean changes,  $-16.23$  vs.  $-11.02$ ), time to first nasal polyp surgery and/or systemic corticosteroid use for nasal polyps (HR = 0.75; 95% CI, 0.55-1.02), or time to first nasal polyp surgery (HR = 0.85; 95% CI, 0.53-1.36) between the groups.

AstraZeneca said that it is now working with the FDA on its next steps. The company further said that it remains committed to bringing benralizumab to patients with CRSwNP.

ORCHID, which is a second phase 3 trial, is ongoing with data readout expected in the second half of 2023, according to AstraZeneca. ORCHID will build on what the company learned about the scientific basis and underlying drivers of

CRSwNP during the OSTRO trial, AstraZeneca continued, such as which patients may most benefit from the medication.

**References:**

[Bachert C, et al. \*J Allergy Clin Immunol.\* 2021;doi:10.1016/j.jaci.2021.08.030.](#)

[Efficacy and safety study of benralizumab in patient with eosinophilic chronic rhinosinustitis with nasal polyps \(ORCHID\). <https://clinicaltrials.gov/ct2/show/NCT04157335>. Updated Feb. 15, 2022. Accessed March 14, 2022.](#)