Eohilia™ (budesonide) – New orphan drug approval

- On February 12, 2024, Takeda announced the FDA approval of Eohilia (budesonide), for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).
    - Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.
- EoE is a chronic, immune-mediated, inflammatory disease localized in the esophagus. The chronic inflammation of EoE can lead to a range of symptoms, which can vary by person and age, and include difficulty swallowing, vomiting and pain.
- The efficacy of Eohilia was established in two randomized, double-blind, placebo-controlled studies (Study 1 and Study 2) in patients with esophageal inflammation defined as ≥ 15 eosinophils/high-power field from at least 2 levels of the esophagus at baseline following a treatment course of a proton pump inhibitor. Study 1 included 318 patients and Study 2 included 92 patients. The primary endpoints were histologic remission and the absolute change from baseline in subject-reported Dysphagia Symptom Questionnaire (DSQ) combined score after 12 weeks of treatment.

Efficacy endpoints	Study 1			Study 2		
	Eohilia	Placebo	Treatment difference	Eohilia	Placebo	Treatment difference
Histological remission	53.1%	1.0%	52.4% (95% CI: 43.3, 59.1)	38.0%	2.4%	35.8% (95% CI: 17.2, 50.0)
Absolute change from baseline in DSQ, least-squares mean (standard errors)	-10.2 (1.5)	-6.5 (1.8)	-3.7 (95% CI: -6.8, -0.6)	-14.5 (1.8)	-5.9 (2.1)	-8.6 (95% CI: -13.7, -3.5)

- After completing Study 1, 48 patients from the Eohilia treatment arm entered a double-blind randomized withdrawal extension study. These patients received Eohilia or placebo for up to an additional 36 weeks. Treatment with Eohilia did not demonstrate a statistically significant difference compared to subjects re-randomized to placebo for prespecified efficacy endpoints based on eosinophil count and/or clinical symptoms measured by the DSQ at week 36.
- Warnings and precautions for Eohilia include hypercorticism and adrenal axis suppression; immunosuppression and increased risk of infection; erosive esophagitis; effect on growth; symptoms of steroid withdrawal in patients transferred from other systemic corticosteroids; other corticosteroid effects; and Kaposi's sarcoma.
- The most common adverse reactions (≥ 2%) with Eohilia use were respiratory tract infection, gastrointestinal mucosal candidiasis, headache, gastroenteritis, throat irritation, adrenal suppression, and erosive esophagitis.
- The recommended dose of Eohilia is 2 mg orally twice daily for 12 weeks.

Continued . . .

- Takeda plans to launch Eohilia by the end of February. Eohilia will be available as a 2 mg/10 mL oral suspension (in single-dose stick packs).