2020. STEPSTONE

Phase 2/OZA/CD/ Induction

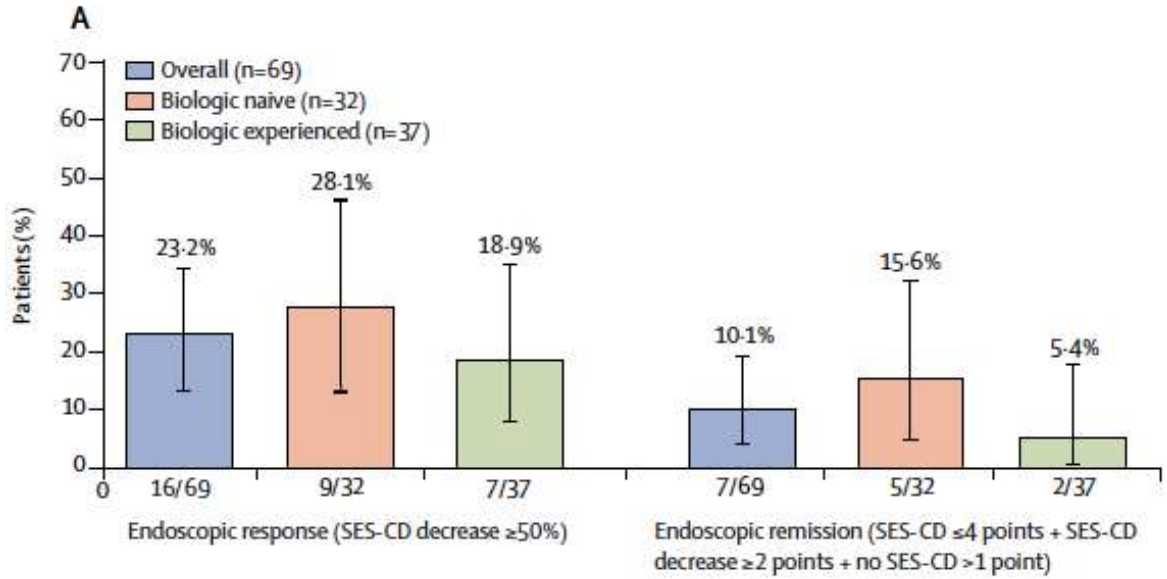
Ozanimod induction therapy for patients with moderate to Severe CD: a single-arm, phase 2, prospective observer-blinded endpoint study

Phase 2, uncontrolled, multicentre trial in adults with mod-severe CD. All patients began treatment with a 7-day dose escalation (4 days on ozanimod 0.25 mg daily followed by 3 days at 0.5 mg daily). Patients then received ozanimod 1.0 mg oral capsule daily for a further 11 weeks, for a 12-w induction period, followed by a 100-w extension.

Primary endpoint: change in Simple Endoscopic Score for Crohn's Disease (SES-CD) from baseline to w12.
ITT analysis

Results:
- W 12, mean change from baseline in SES-CD was −2.2 (SD 6.0);
- Endoscopic response w12: 16 (23.2%, 95% CI 13.9–34.9)
- Endoscopic remission w12: 10.1%.
- Biologic naïve 28.1% vs biologic experienced 18.9% had endoscopic response.

Conclusions:
Endoscopic, histological, and clinical improvements were seen within 12 weeks of initiating ozanimod therapy in patients with moderately to severely active Crohn's disease.



Feagan BG et al. Lancet. 2020;819-828