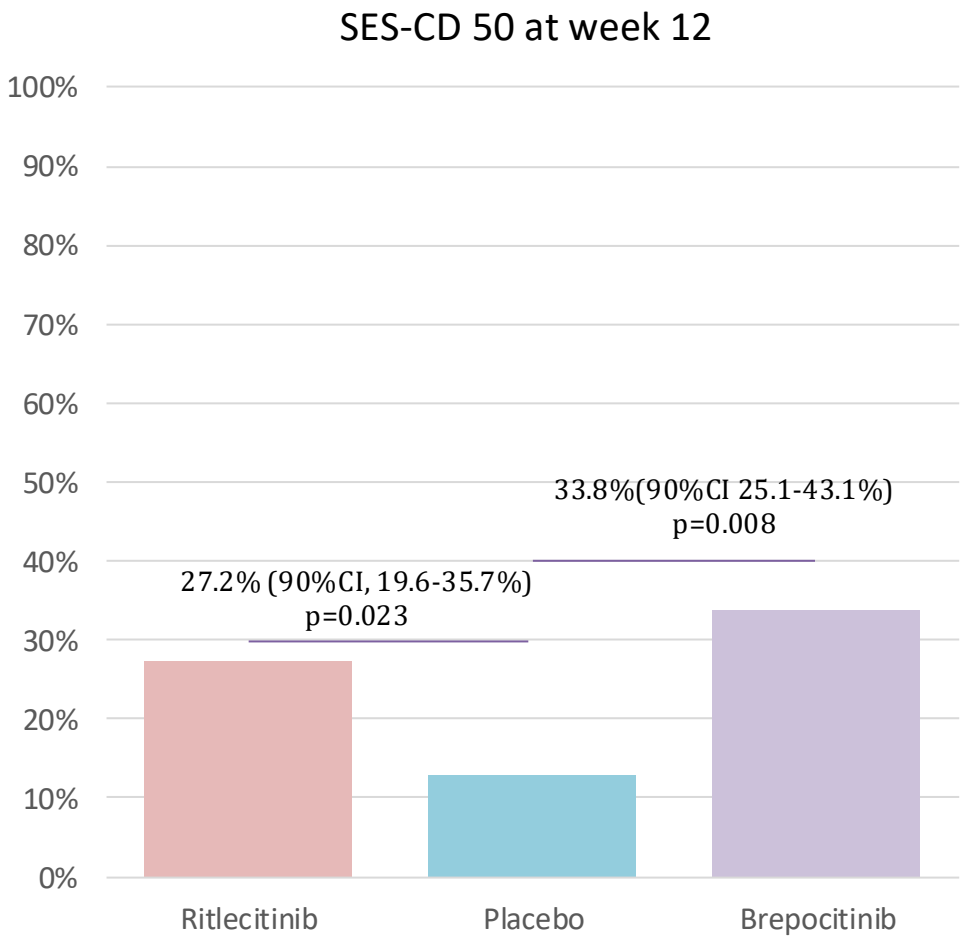
2026. PIZZICATO

RCT/ Ritlecitinib & brepocitinib /CD/Induction

Once-daily oral ritlecitinib or brepocitinib versus placebo in patients with moderate-to-severely active Crohn's disease (PIZZICATO): an international, randomised, phase 2a trial

Multicenter randomised, placebo-controlled, parallel-group phase 2A trial.
Adult patients with mod-severe active CD were randomised to receive once-daily oral ritlecitinib (200mg for 8 weeks then 50 mg for 4 weeks), brepocitinib (60mg for 12 weeks) or placebo in the induction phase. For the following 52 weeks it was an open-label extension phase with a reduced doce of 50mg ritlecitinib or 30mg brepocitinib.

Primary endpoint: Simple Endoscopic Score (SES) for CD (SES-CD 50; defined as ≥50% reduction from baseline) at Week 12 (ritlecitinib versus placebo; brepocitinib versus placebo). The endpoint was changed from clinically-meaningful endoscopic improvement by protocol amendment during study execution.



Results: N=244

- At week 12, SES-CD 50 was achieved by 27.2% (90%CI, 19.6-35.7%) ritlecitinib, 33.8%(90%CI 25.1-43.1%) brepocitinib and 12.8% (90%CI 7.1-19.9%) placebo. Ritlecitinib vs placebo, p=0.023; brepocitinib vs placebo, p=0.008.

Conclusion:
Ritlecitinib and brepocitinib showed significant improvement in the primary outcome vs placebo for modseverely active CD, with acceptable safety profiles.

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