2022. HIBISCUS I&II

Phase 3/ ETR vs ADA/ UC/ Induction

Etrolizumab vs placebo vs ADA phase 3 RCT in mod-sev UC induction of remission

Randomised, double-blind, placebo-controlled and active-controlled studies.
Patients with moderately to severely active UC naïve to antiTNF were randomised to:
Etrolizumab 105mg q4w, Adalimumab (160,80) 40mg q2w or placebo.
HBISCUS I and II identically designed.

Primary endpoint HIBISCUS I remission w10 with ETR vs placebo.
Secondary endpoints w 10: endoscopic improvement, clinical response, histologic response, histologic remission, endosocpica remission, change in stool freq.from baseline w6, change in RB w6

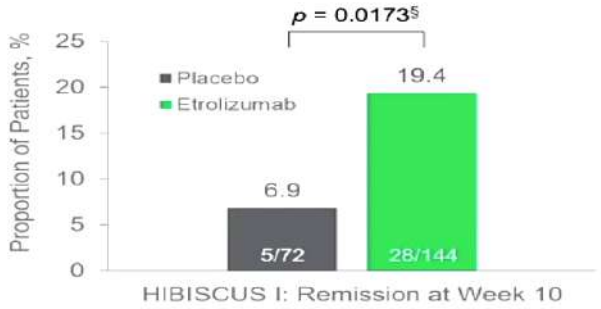
Results:

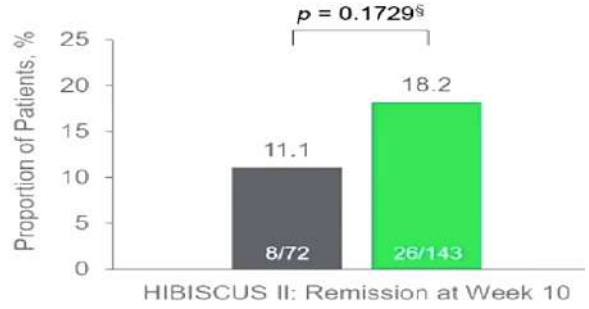
- HIBISCUS I remission w10: 19.4% ETR vs 6.9% placebo, p=0.017.
- HIBISCUS II w10: 18.2% ETR vs 11.1% placebo, p=0.17,
- Pooled analysis: Etrolizumab not superior to Adalimumab for induction of remission at w10.

Secondary endpoints:

- Endoscopic improvement 22.2%pbo vs 40.3% ETR, p=0.017
- Histologic remission w10: 16.1% pbo vs 42.5% ETR, p=0.017

Conclusions:
ETR met primary endpoint of remission w10 in HIBISCUS I but not HIBISCUS II. ETR induced endoscopic improvement and histologic remission w10 vs pblo in HIBISCUS I





§p value based on analysis adjusting for multiplicity and stratification factors.
MCS, Mayo Clinic total score; RB, rectal bleeding.
Remission: MCS ≤ 2 with individual subscores ≤ 1 and RB subscore of 0.

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Rubin DT et al. Lancet. 2022; 7(1):17-27