2020. U-ACHIEVE

Phase 2B/UPA/ UC /Induction

Efficacy of upadacitinib in a randomized trial of patients with active UC

Phase 2b, double blind RCT. 8-week induction therapy with placebo or UPA at 7.5 mg, 15 mg, 30 mg, or 45 mg extended release once daily.

Primary endpoint: clinical remission according to the adapted Mayo score, defined as stool frequency subscore of 1, rectal bleeding subscore (RBS) of 0, and endoscopic subscore of 1 by central reading at week 8.

Results:

- At w8, 8.5%, 14.3%, 13.5%, and 19.6% of patients receiving 7.5 mg, 15 mg, 30 mg, or 45 mg UPA, respectively, achieved clinical remission vs none of the placebo (p 0.052, p 0.013, p 0.011, and p 0.002 vs placebo, respectively).
- Endoscopic improvement at w8, defined as endoscopic subscore of 1, was achieved in 14.9%, 30.6%, 26.9%, and 35.7% of patients on UPA 7.5 mg, 15 mg, 30 mg, or 45 mg, respectively, vs 2.2% placebo (p =0.033, p < .001, p < .001, and p < .001 vs placebo, respectively).

Conclusion:
8 weeks of treatment with UPA was more effective than placebo for inducing remission in patients with moderately to severely active UC.

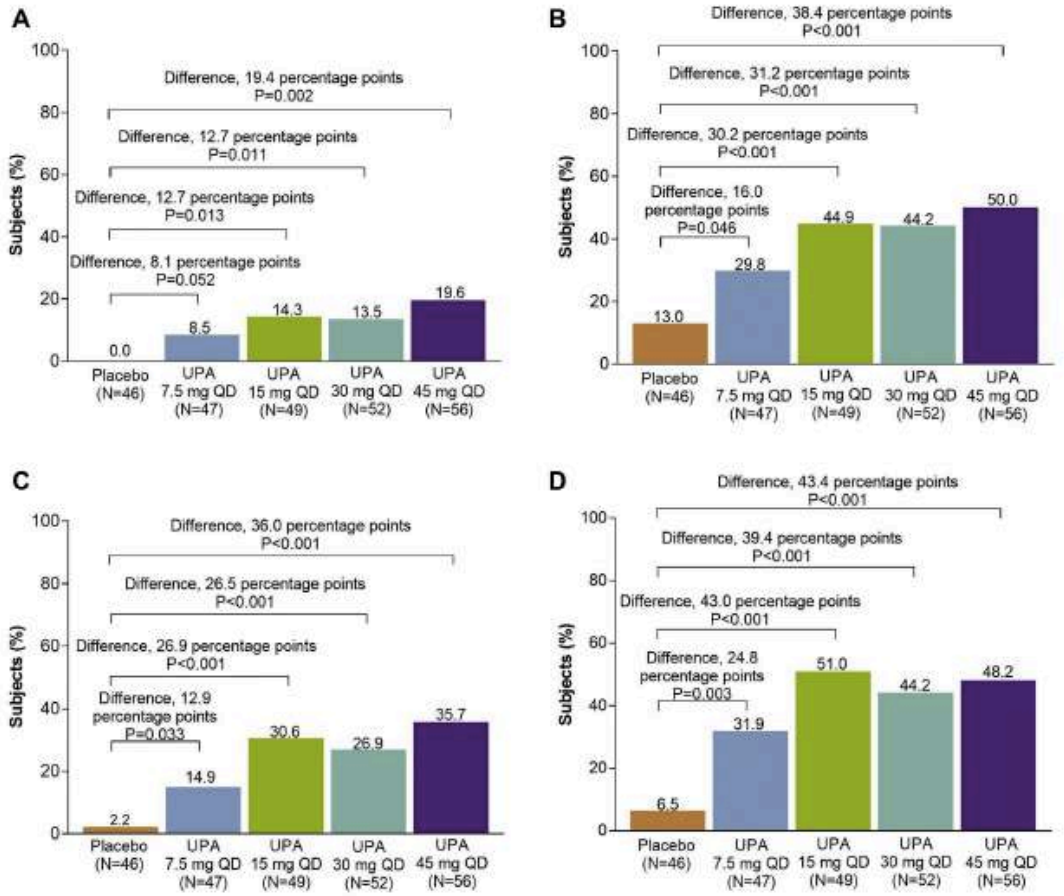

Figure 2. Proportion of patients with (*A*) clinical remission according to the adapted Mayo score, (*B*) clinical response according to the adapted Mayo score, (*C*) endoscopic improvement, and (*D*) histologic improvement. QD: once daily; UPA, upadacitinib.

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