

## 2023. U-ACHIEVE maintenance

RCT/UPA/UC/ Maintenance

Multicentre, randomised, phase 3, double-blind trial. Patients with moderately-severely active ulcerative colitis who were included into the phase 2b or phase 3 induction trials and who had clinical response per adapted Mayo score at week 8, were randomized to placebo, UPA 15mg or UPA 30mg.

Primary endpoints: Clinical remission per adapted Mayo score at week 52.

### Results:

- Of the 987 patients who received UPA 45mg/d in the induction trials, 681 who responded were randomised.
- Clinical remission at week 52: UPA 15mg (40.4%) vs 30mg (53.6%) vs placebo (10.8%);  $p < 0.001$  vs placebo for both.
- Adverse events that were more frequent than placebo: Herpes zoster, hepatic disorders, CK elevation, neutropenia

### Conclusion:

Both maintenance doses of upadacitinib showed a positive benefit-risk profile in patients with moderately to severely active ulcerative colitis.

**Efficacy and safety of upadacitinib maintenance therapy for moderately active UC in patients responding to 8 week induction therapy (U-ACHIEVE Maintenance): overall results from the randomised, placebo-controlled, double-blind, phase 3 maintenance study**

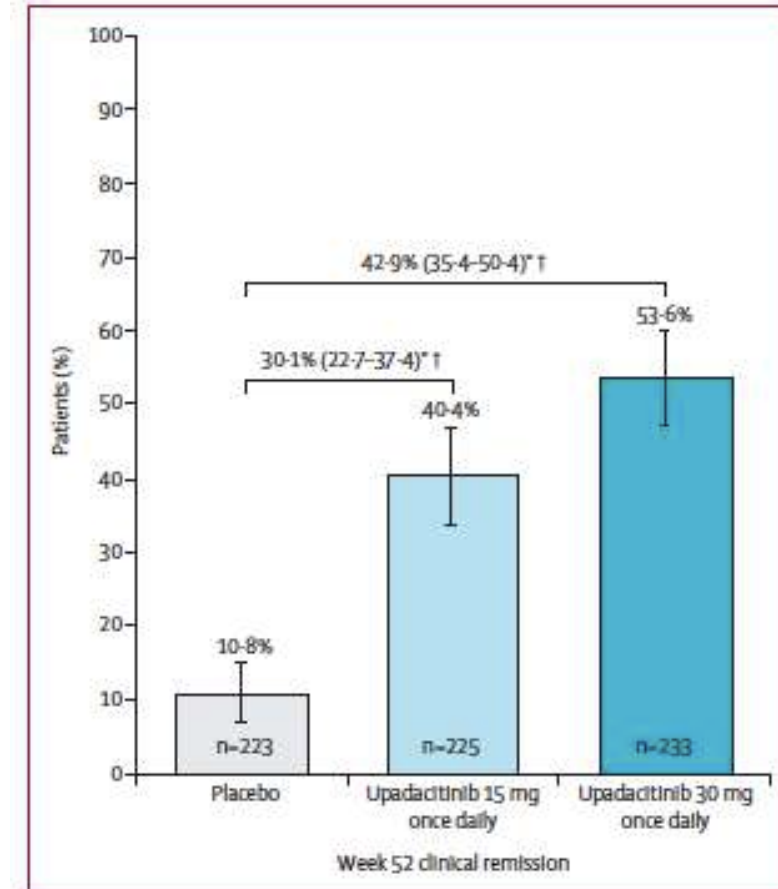


Figure 2: Clinical remission per adapted Mayo score at week 52 (intention-to-treat population; n=681)

