2017. Golimumab-Japan

RCT/Golimumab / UC/ Maintenance

Efficacy and safety of golimumab 52-week maintenance therapy in Japanese patients with moderate to severely active ulcerative colitis: a phase 3, double-blind, randomized, placebo-controlled study-(PURSUIT-J study)

Phase 3, double-blind, placebo-controlled, parallel group, randomized withdrawal study.
Patients with moderately-severe active UC received 200mg GOLI SC at week 0 and 100mg at week 2 durnig the 6-week open-label induction. Patients who responded entered maintenance and were randomized to 100mg q4w or placebo for 52 w.

Primary endpoint: Maintenance of clinical response through the end of maintenance at w54.

Results: N=144

- Of the 144, 123 (85.4%) completed the induction phase and 63 (43.8%) were randomized.
- Clinical response was maintained at w54 in 56.3% (18/32) GOLI vs 19.4% (6/31) placebo, p<0.05.
- Clinical remission at w30 and w54 GOLI 50% vs 6.5%placebo, p<0.05.
- Mucosal healing at w54 was 59.4% GOLI vs 16.1% placebo.

Conclusion:
Golimumab SC treatment maintained clinical efficacy through week 54 among induction responders, and no new safety signals were observed in the patients with moderate to severely active UC.

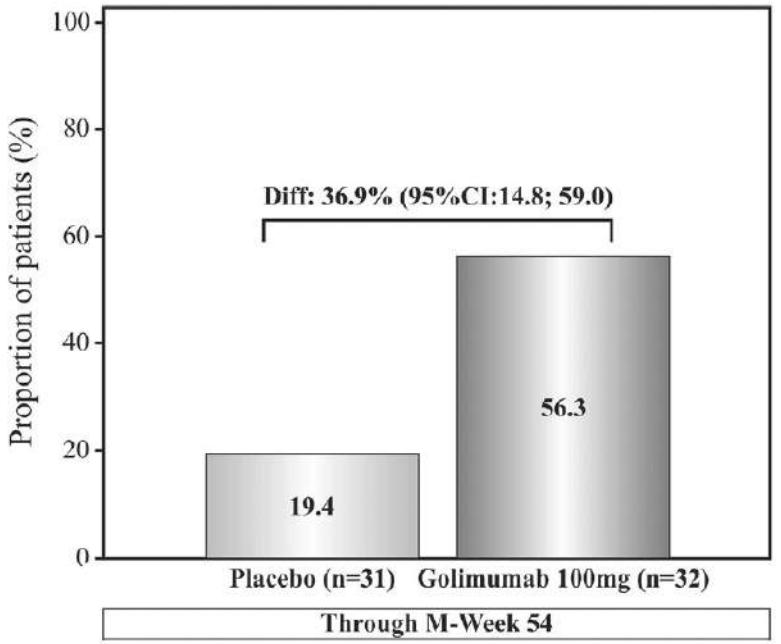

Fig. 2 Proportion of patients with clinical response through M-week 54, Full analysis set-DB. *CI* confidence interval, *DB* double-blind, *M-week* maintenance week

Hibi T et al. J Gastroenterol. 2017; 52: 1101-1111