2023. PROTECT 1/2

RCT/ LT-02 /UC/ Induction&Maintenance

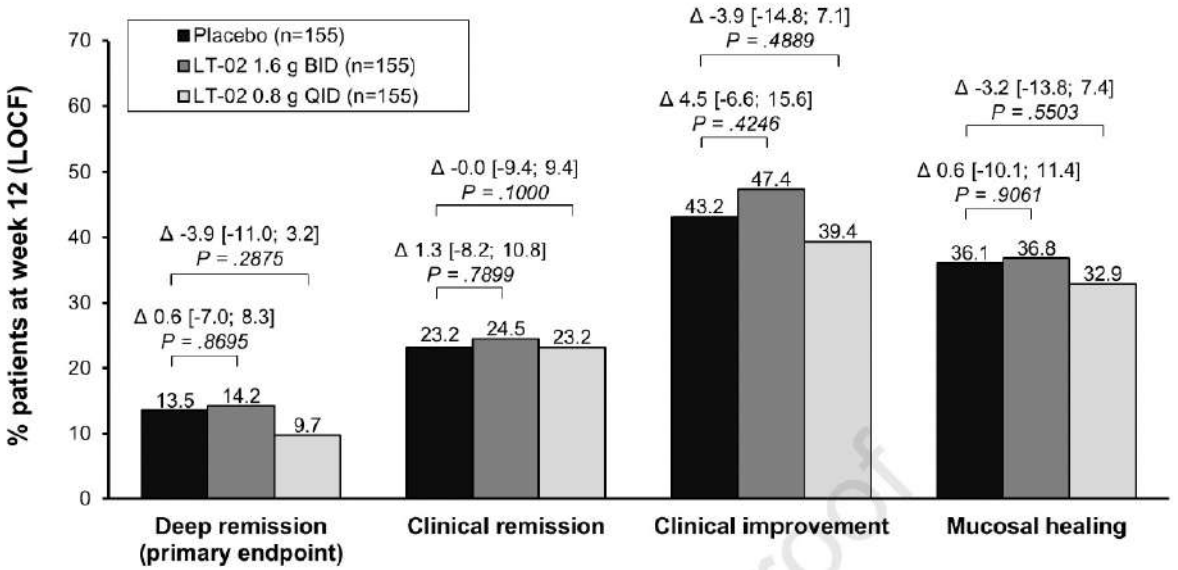
Modified-release Phosphatidylcholine (LT-02) for Ulcerative Colitis: Two Doubleblind, Randomized, Placebo-controlled Trials

Multicenter double-blind, randomized, placebo-controlled study
Patients with mild-moderate UC were randomized to 0.8 g LT-02* 4 times daily (QID), 1.6 g LT-02 twice daily (BID), or placebo.
Patients in remission at w12 were randomized to LT-02, mesalazine (1.5g/d) or placebo.

Primary endpoints: Deep remission at w12 & w48 for maintenance.
(defined as an mDAI score ≤ 1 with score of 0 for rectal bleeding & stool frequency, & ≥ 1 point decrease in the mucosal appearance score from baseline

Results: N= 466 (of the 762 planned in PCG2) & N=150 (of 400 planned)
- PG2 was terminated early for futility after a pre-specified interim analysis.
- No differences at w12 were found between LT-02 QID, BID and placebo, 9.7% vs 14.2% vs 13.5% respectively.
- No differences at w48 between LT-02 vs mesalazine vs placebo, 49.3% vs 50% vs 43.2% respectively.

Conclusion:
Despite prior evidence of beneficial effects of PC in phase 2 trials, induction study with LT-02 in patients with mild-moderate UC was terminated prematurely for futility. LT-02 was safe and well tolerated.



*LT-02 is a novel modified-release phosphatidylcholine (PC) formulation. PC is the predominant phospholipid species present in the intestinal mucus

Dignass A et al. Clin Gastroenterol Hepatol.2023