2015. PURSUIT-IV

RCT/Golimumab/ UC /Induction

Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis

Multicentre, randomised, double-blind, placebo-controlled, integrated Phase 2/3 dose-finding/dose-confirming study.
Patients with mod-severe UC were randomised:
-Phase 2 to single IV infusion (1mg/kg, 2 or 4 mg/kg IV) or placebo.
-Phase 3 (enrolment stopped sooner due to the lower than expected efficacy in phase 2) patients were randomized to 2 or4 mg/kg IV or placebo.
Duet to insufficient power for the Phase 3 the results are considered exploratory.

Primary endpoints: To evaluate dose-response and efficacy at week 6

Results: N= 291
- No dose-response was observed In the Phase 2.
- Clinical response at week 6 2mg/kg 44% vs 4mg/kg 41.6% vs placebo 30.1, p=0.081 and 0.145 respectively.
- Higher levels of golimumab were associated with greater proportions of clinical response and Mayo score improvement.

Conclusion:
Efficacy with single-dose golimumab IV induction was lower than expected and less than observed in the SC induction study. No new safety findings were observed.

Table 2 | Efficacy findings: All randomised patients (excluding noncompliant site)

Variable	Placebo (*N* = 73)	Golimumab 1 mg/kg (*N* = 61)	Golimumab 2 mg/kg (*N* = 75)	Golimumab 4 mg/kg (*N* = 77)	Golimumab Combined (*N* = 213)
Clinical response at week 6, *n* (%)*†	22 (30.1)	22 (36.1)	33 (44.0)	32 (41.6)	87 (40.8)
P value		0.467	0.081	0.145	0.104
Clinical remission at week 6, n (%)*†	8 (11.0)	6 (9.8)	12 (16.0)	10 (13.0)	28 (13.1)
P value		0.832	0.370	0.702	0.627
Mucosal healing at week 6, *n* (%)*†	24 (32.9)	17 (27.9)	26 (34.7)	29 (37.7)	72 (33.8)
P value		0.531	0.818	0.540	0.885

Rutgeerts P et al. Alim Pharmacol Ther. 2015. 42: 504–514