2022. AJM300

Phase 3/AJM300/ UC/induction

AJM300 (carotegrast methyl), an oral antagonist of alfa4-integrin, As induction therapy for patients with moderately active UC: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial

Randomised, double-blind, placebo controlled trial. Patients with active UC with inadequate response to mesalazine.
2 phases, a treatment phase and an open-label re-treatment phase.
2 arms: AJM300 (969mg) orally 3 times per day or placebo for 8w and continued for 24w if endoscopic remission not achieved.

Primary endpoint: clinical response at w8.

Results:
- At w8, clinical response 45% AJM300 vs 21% placebo, p=0.00028.
- Adverse events no differences among groups.
- Most common adverse event nasopharyngitis.

Endpoint	PBO, n (%) (n=101)	AJM300, n (%) (n=102)	Percent difference (95% CI)	P value
Clinical response	21 (20.8)	46 (45.1)	24.3 (11.4,36.1)	0.0003
Clinical remission	14 (13.9)	23 (22.5)	8.7 (-2.0,19.2)	0.1089
Symptomatic remission	22 (21.8)	42 (41.2)	19.4 (6.6,31.3)	0.0029
Endoscopic improvement	27 (26.7)	56 (54.9)	28.2 (14.7,40.2)	<0.0001
Endoscopic remission	3 (3.0)	14 (13.7)	10.8 (3.1,19.0)	0.0057

Conclusion:
AJM300 was well tolerated and induced a clinical response in patients with moderately active UC who had inadequate response or intolerance to mesalazine. AJM300 could be a novel induction therapy for the treatment of patients with mod-active UC.

Matsuoka K et al. Lancet Gastroneterol Heatol.2022; 7(7);648-657