2016. ELDELUMAB

RCT/Eldelumab/ UC/Induction

Eldelumab [Anti-IP-10] Induction Therapy for Ulcerative Colitis: A Randomised, Placebo- Controlled, Phase 2b Study

Multicentre randomised, placebo-controlled trial. Patients with moderate-severe UC were randomised to eldelumab 15mg/kg or 25 mg/kg IV on days 1 and 8 and every other week thereafeter or placebo

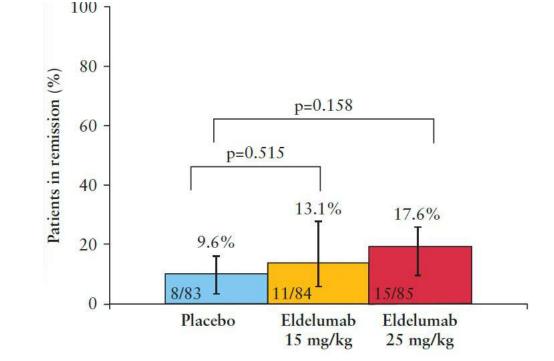
<u>Primary endpoint</u>: clinical remission [Mayo score ≤ 2; no subscore > 1] at Week 11

Results: N=252

- Clinical remission at w11: ELDEL15 13.1%, ELDEL25 17.6% and placebo 9.6%
- Clinical response at w 11: ELDEL15 44%, ELDEL25 47.1% and placebo 31.3%
- Mucosal healing w11: ELDEL15 29.8%, ELDEL25 31.8%, and placebo 27.7%

Conclusion:

The primary endpoint was not achieved with induction treatment with eldelumab 15 or 25 mg/kg in patients with UC. Trends towards clinical remission and response were observed in the overall population and were more pronounced in anti-TNF naïve patients.



*Eldelumab: Fully human monoclonal antibody againts Interferon- γ -inducible protein-10

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