## 2022. ABX464

## RCT/Obefazimod/CD/ Induction

Phase 2b, double-blind, randomised, placebo-controlled trial. Patients with moderate to severe ulcerative colitis were randomized to daily oral ABX464 (100mg, 50mg, 25mg) or matched placebo.

<u>Primary endpoints:</u> Change from baseline in modified Mayo score (MMS) at week 8.

## Results:

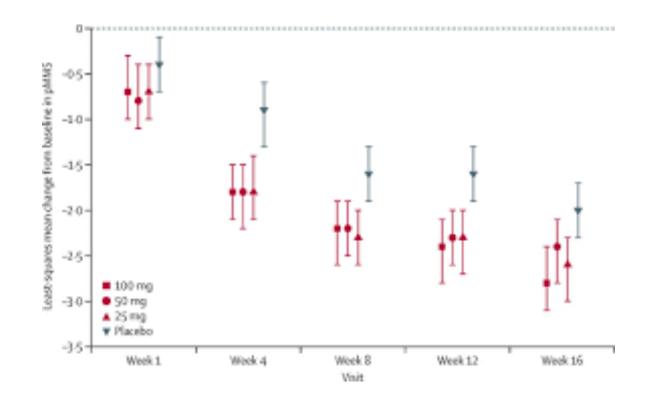
- At week 8 median change from baseline in MMS was significantly superior in all ABX464 doses (-2.9 in 100mg; -3.2 in 50mg; -3.1 in 25mg vs -1.9 placebo, p=0.0039, p=0.0003, p=0.0010 respectively against placebo.
- Most frequent adverse event was headache.

## **Conclusion:**

All doses of ABX464 significantly improved moderate t severe, active ulcerative colitis compared with placebo, as measured by changes in MMS from baseline to week 8.

\*Obefazimod is a small molecule that selectively upregulates miR-124 in immune cells.

ABX464 (obefazimod) for moderate to severe, active ulcerative Colitis: a phase 2b, double-blind, randomised, placebo-controlled Induction trial and 48 week, open-label extension



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