

CORRELATION OF MIR-124 UPREGULATION AND PK PARAMETERS IN BLOOD OF PATIENTS WITH MODERATE-TO-SEVERE ULCERATIVE COLITIS RECEIVING OBEFAZIMOD FOR 16 WEEKS

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In a 16-week phase 2b study of 205 ulcerative colitis patients, obefazimod dose-dependently increased blood miR-124 levels, with upregulation correlating significantly with the metabolite N-Glu pharmacokinetics rather than the parent drug.

KEY POINTS

- Obefazimod at 25, 50, and 100 mg once daily produced dose-dependent increases in miR-124 copy numbers (medians 2289, 5038, and 8672 respectively).
- miR-124 upregulation correlated significantly with N-Glu AUC ($r=0.394$, $p<0.001$) and Cmax ($r=0.349$, $p<0.001$), but showed weaker or no significant correlation with parent drug pharmacokinetics.
- Dose-stratified analysis showed strongest correlations at 25 mg and 50 mg doses, with loss of significant correlation at 100 mg suggesting a possible saturation effect.
- The findings indicate N-Glu is the dominant driver of miR-124 expression, consistent with its longer half-life and higher exposure compared to obefazimod.
- This pharmacodynamic analysis may inform understanding of obefazimod's anti-inflammatory mechanism in moderate-to-severe ulcerative colitis.

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