

From Evolution to Revolution: New Mechanisms of Action in Ulcerative Colitis (Abivax) (Complete Session)

Silvio Danese

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Presentation

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The speaker reported that obamod (OB), an investigational oral microRNA-124 modulator, met primary efficacy endpoints in two phase 3 induction trials (ABTC-1 and ABTC-2) for moderate to severely active ulcerative colitis at week 8, with a safety profile showing no signal for immune suppression.

KEY POINTS

- In ABTC-1 (639 patients), the speaker stated that both 25mg and 50mg once-daily doses met the FDA primary endpoint of clinical remission with approximately 20% effect size over placebo (2.5% placebo rate), and both doses met EMA co-primary endpoints.
- In ABTC-2 (636 patients), the speaker reported that the 50mg dose met the FDA primary endpoint (13% effect size over 6.3% placebo), while the 25mg dose did not achieve statistical significance for the FDA endpoint but met the EMA co-primary endpoints.
- The speaker noted that 21% of enrolled patients had failed a JAK inhibitor and there was no limit on prior treatment failures, with the 50mg dose showing meaningful efficacy across all lines of prior advanced therapy exposure in subgroup analyses.
- The speaker stated that the most common adverse event was headache, described as mild to moderate, occurring early in treatment (within 1-2 days), lasting 1-2 days, and often responsive to acetaminophen.
- The speaker reported no deaths, no signal for immune suppression, serious infections, or malignancies above placebo rates, and that treatment discontinuation rates due to adverse events were not higher than placebo for the 50mg dose.
- The speaker explained that obamod binds to the nuclear cap-binding complex to enhance expression of microRNA-124, which is diminished in UC mucosa, thereby restoring mucosal homeostasis through anti-inflammatory effects including reduced STAT3, IL-6 signaling, and Th17 cell stabilization.

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