Safety and efficacy of Profermin(R) to induce remission in ulcerative colitis

AIM: To test the efficacy and safety of Profermin(R) in inducing remission in patients with active ulcerative colitis (UC).

METHODS: The study included 39 patients with mild to moderate UC defined as a Simple Clinical Colitis Activity Index (SCCAI) > 4 and < 12 (median: 7.5), who were treated open-label with Profermin(R) twice daily for 24 wk. Daily SCCAI was reported observer blinded via the Internet.

RESULTS: In an intention to treat (ITT) analysis, the mean reduction in SCCAI score was 56.5%. Of the 39 patients, 24 (62%) reached the primary endpoint, which was proportion of patients with ≥ 50% reduction in SCCAI. Our secondary endpoint, the proportion of patients in remission defined as SCCAI ≤ 2.5, was in ITT analysis reached in 18 of the 39 patients (46%). In a repeated-measure regression analysis, the estimated mean reduction in score was 5.0 points (95% CI: 4.1-5.9, P < 0.001) and the estimated mean time taken to obtain half the reduction in score was 28 d (95% CI: 26-30). There were no serious adverse events (AEs) or withdrawals due to AEs. Profermin(R) was generally well tolerated.

CONCLUSION: Profermin(R) is safe and may be effective in inducing remission of active UC.