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## VSL#3<sup>®</sup> Probiotic-Mixture Induces Remission in Patients with Active Ulcerative Colitis<sup>1</sup>

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### Background

- Intestinal bacteria have been implicated in the initiation and perpetuation of inflammatory bowel disease (IBD)<sup>2</sup>
- In contrast, "probiotic bacteria" have properties possibly effective in treating and preventing relapse of IBD<sup>3-9</sup>
- A probiotic preparation consisting of a mixture of eight lactic acid bacterial species (VSL#3<sup>®</sup>) appears to have anti-inflammatory activities both with the live organism<sup>7,10-13</sup> as well as through its DNA<sup>14</sup>

### Objective

- To evaluate the safety and efficacy of VSL#3<sup>®</sup> and its components and determine the number of patients achieving an improvement in ulcerative colitis (UC) activity from baseline following 6 weeks of VSL#3<sup>®</sup> therapy as measured by the Ulcerative Colitis Disease Activity Index (UCDAI)<sup>1</sup>

### Methodology

- Thirty-four ambulatory patients with active UC received open-label VSL#3<sup>®</sup>, 3,600 billion bacteria daily in two divided doses for 6 weeks<sup>1</sup>
- The presence of biopsy-associated bacteria was detected using a nucleic acid-based method; VSL#3 species was detected by DNA sequencing of 16S rRNA<sup>1</sup>

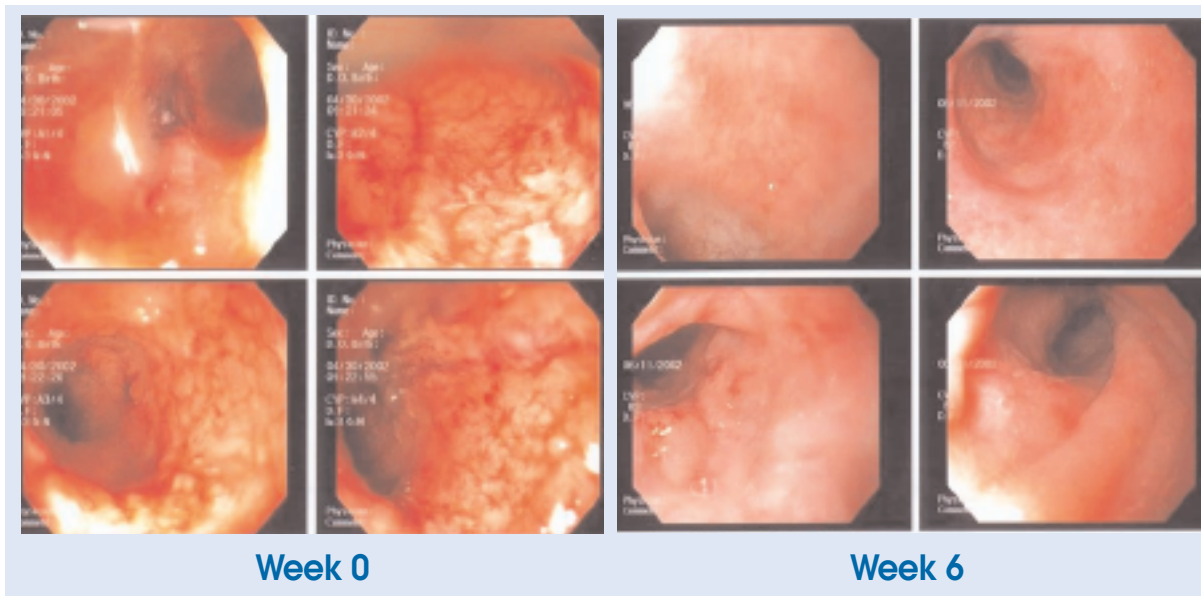
### Results

In patients treated with probiotic mixture VSL#3<sup>®</sup> not responding to conventional therapy:

- **Intent-to-treat analysis demonstrated remission (UCDAI  $\leq$  2) in 53% (n = 18); response (decrease in UCDAI  $\geq$  3, but final score  $\geq$  3) in 24% (n = 8); no response in 9% (n = 3); worsening in 9% (n = 3); and failure to complete the final sigmoidoscopy assessment in 5% (n = 2)<sup>1</sup>**
- **There were no biochemical or clinical adverse events related to VSL#3<sup>®</sup>**<sup>1</sup>

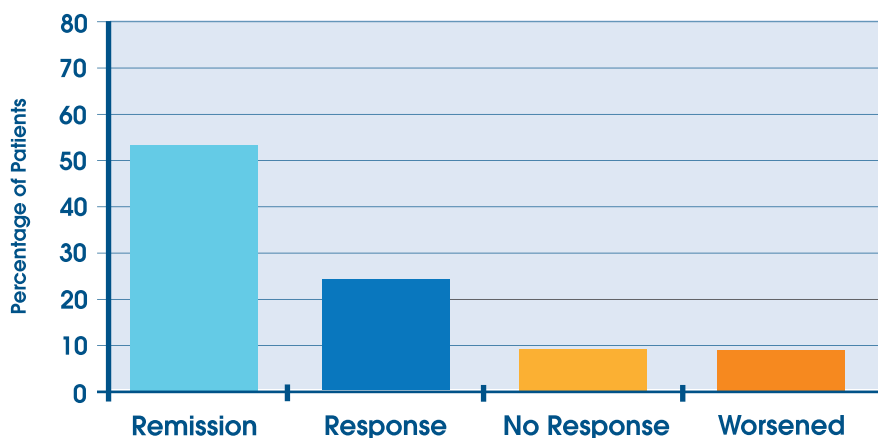
# Key Findings: VSL#3<sup>®</sup> Acute UC Results<sup>15</sup>

## Before and after VSL#3 therapy



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## Response in patients with active UC receiving VSL#3<sup>®</sup> after 6 weeks<sup>1</sup>



Intent-to-treat analysis following 6 weeks of VSL#3<sup>®</sup> treatment in patients with active ulcerative colitis.

Remission was achieved in 53% (n = 18), response in 24% (n = 8), no response in 9% (n = 3), and worsening of disease activity in 9% (n = 3). Two patients did not complete the final endoscopic assessment.<sup>1</sup>

Adapted from Biblioni, et al.

Treatment of patients with mild to moderate UC, not responding to conventional therapy, with the probiotic mixture VSL#3<sup>®</sup> results in:

- 53% Remission rate<sup>1</sup>
- 24% Response rate<sup>1</sup>
- 77% Combined Remission/Response rate<sup>1</sup>

No adverse events were noted other than mild bloating<sup>1</sup>

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