MedicalXpress

FDA approves mirikizumab, a promising induction and maintenance therapy for ulcerative colitis

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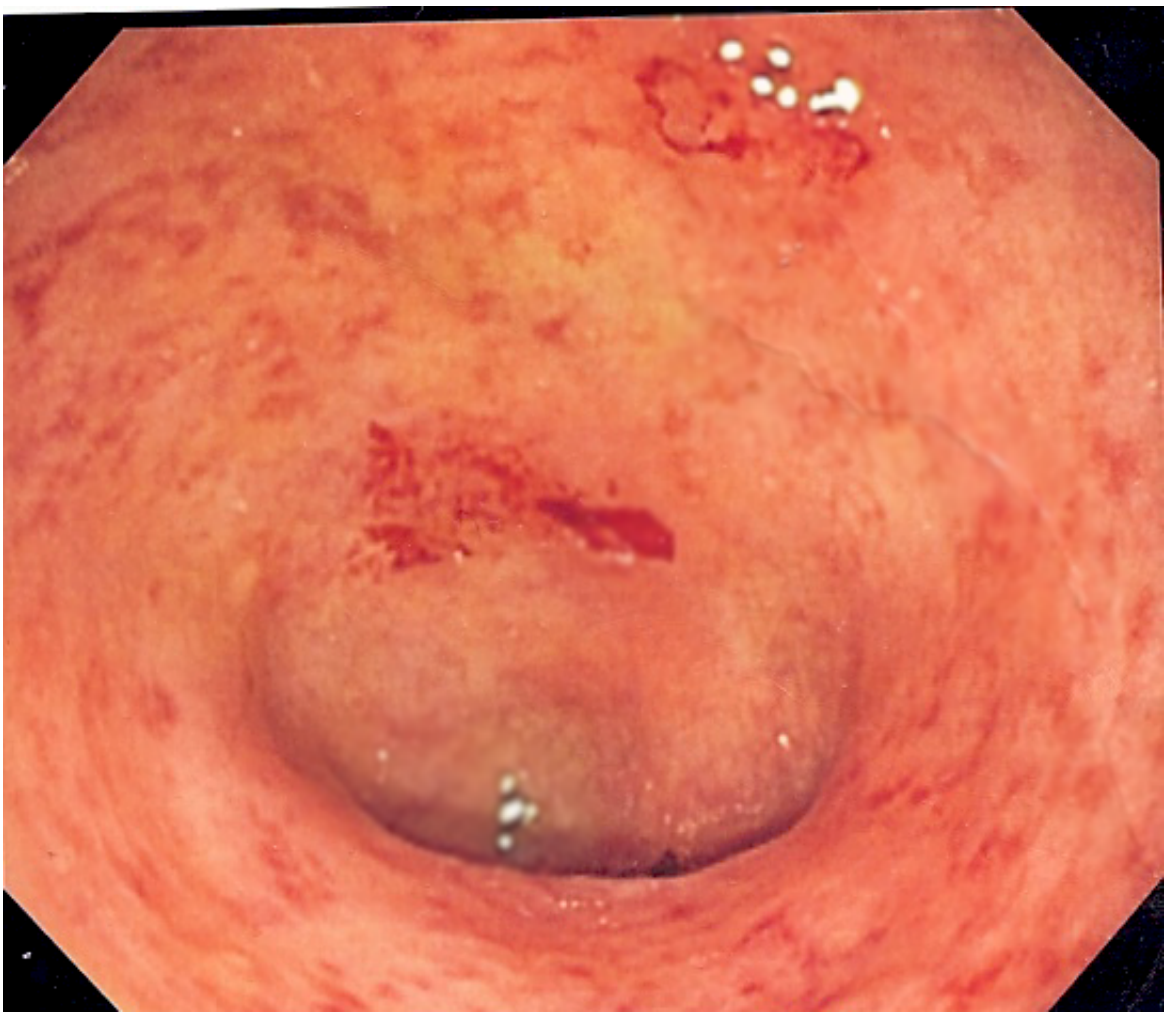

Endoscopic image of a bowel section known as the sigmoid colon afflicted with ulcerative colitis. The internal surface of the colon is blotchy and broken in places. Credit: Samir/Wikipedia

The U.S. Food and Drug Administration (FDA) approved mirikizumab, on October 26, 2023, a highly effective new treatment for ulcerative colitis (UC), offering a new option to patients battling this chronic and debilitating inflammatory bowel disease.

This therapy offers a safe and effective treatment option for patients with moderate-to-severely active UC who have yet to achieve rapid and lasting improvements on currently available therapies. Unlike existing treatments for UC, mirikizumab also offers relief from a key symptom—bowel urgency—that greatly impacts patients' quality of life.

Ulcerative colitis affects millions of people worldwide. The induction and maintenance of remission are critical goals in the management of UC. However, existing therapies may not provide sufficient efficacy or patients may have trouble tolerating them.

"Mirikizumab is the first antibody targeting p19/interleukin-23 to be approved for the treatment of ulcerative colitis. Its performance in both induction and maintenance phases of the clinical trials is truly impressive," said Bruce Sands, MD, MS, senior author of the clinical trial study published in the *New England Journal of Medicine* (*NEJM*). Dr. Sands is Chief, Dr. Henry D. Janowitz Division of Gastroenterology, Mount Sinai Health System, and the Dr. Burrill B. Crohn Professor of Medicine, Icahn School of Medicine at Mount Sinai. Dr. Sands is also a paid consultant for Lilly U.S., LLC.

"The Lucent program was the first clinical trial program that addressed bowel urgency in a meaningful way," said Marla C. Dubinsky, MD, co-author of the *NEJM* study, Co- director, Susan and Leonard Feinstein Inflammatory Bowel Disease Clinical Center, and Professor of Pediatrics, and Medicine, Icahn Mount Sinai. "It is one of the most

burdensome patient-reported symptoms, and a drug that achieves bowel urgency remission is an outcome of great importance to our patients with UC."

As published in *NEJM*, mirikizumab demonstrated exceptional results in both the induction and maintenance arms of the phase 3, randomized, double-blind, placebo-controlled trials in adults with moderately-to-severely active UC.

Induction Phase (LUCENT-1 Trial)

During the induction phase, the LUCENT-1 trial evaluated the efficacy of mirikizumab in inducing clinical remission at week 12 in patients with moderate to severely active UC.

The study enrolled 1,281 patients who were randomized 3:1 to receive intravenous 330mg mirikizumab or placebo every four weeks for 12 weeks. A significantly greater proportion of mirikizumab-treated patients achieved clinical remission at week 12 (mirikizumab: 24.2%; placebo: 13.3%; p