# Baseline Characteristics and Treatment Persistence in UK Patients with Moderate-to-Severe UC Following 12-week Mirikizumab Induction: Real-World Data from IBD BioResource



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## OBJECTIVE

- To present a retrospective, interim analysis of a multicentre observational study, describing
  - patient baseline characteristics, and
  - treatment persistence at 12 weeks in routine UK clinical practice.

## CONCLUSION

- **Induction therapy with mirikizumab was successfully continued through to week 12 in this treatment experienced real-world UK population.**
- 1-year treatment persistence and effectiveness data will be disclosed in the future.

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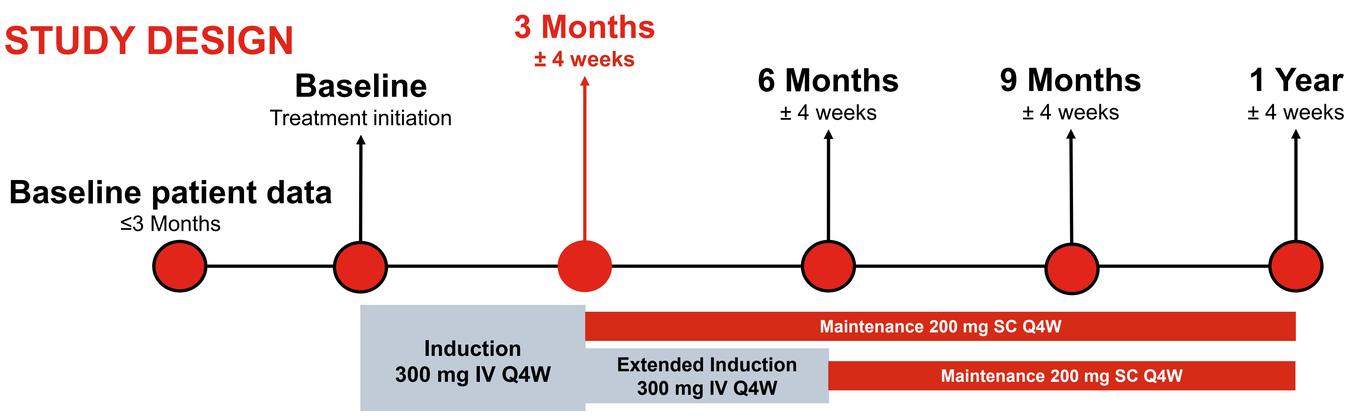
## STUDY DESIGN




### Selection Criteria

Inclusion

- Age ≥18 years
- Diagnosis of moderate-to-severe ulcerative colitis (UC) as registered in the NIHR IBD BioResource
- Have received ≥1 dose of mirikizumab for UC per standard clinical practice

Exclusion

- Prior treatment with anti-IL-23p19 antibodies for any indication, including investigational use
- Patients with Crohn's disease

## BACKGROUND

- UC is a chronic inflammatory disease affecting the colon and rectum.[1] Current therapies are limited by primary non-response or loss of efficacy.[1]
- Mirikizumab, a humanised IgG4 monoclonal anti-interleukin-23 antibody, has demonstrated long-term efficacy and safety in adult patients with moderately to severely active UC in the LUCENT clinical trial programme.[2,3]
- However, real-world evidence studies on mirikizumab have been limited.[4-6]

## METHODS

### Study Population and Statistical Analysis

- Adult patients (N=78) of the UK-wide NIHR IBD BioResource panel of IBD patients who initiated mirikizumab treatment for UC with a 3-month follow-up visit. Data were collected prospectively across 20 NHS sites for baseline and analysed retrospectively, with 25 sites currently participating.
- Analyses were descriptive and reported as mean (SD), median (IQR), and number (percent [%]). For categorical variables, missing values were included as their own category. Kaplan-Meier analysis was used to describe time to discontinuation up to 12 weeks (N=71[a]).

*Data presented here differ from those on the accepted submission abstract, given the availability of further data since submission. Results are based on an interim data release, and are subject to change with future data releases including additional follow-up data.*

## Baseline Characteristics and Prior Therapies

- Most patients who initiated mirikizumab were male. 41.0% had extensive UC, and 85.9% had prior experience with advanced therapies such as TNFi[b] (66.7%), vedolizumab (60.3%), JAKi[c] (28.2%) and ustekinumab (25.6%).

**Table 1: Patient Demographics and Clinical Characteristics**

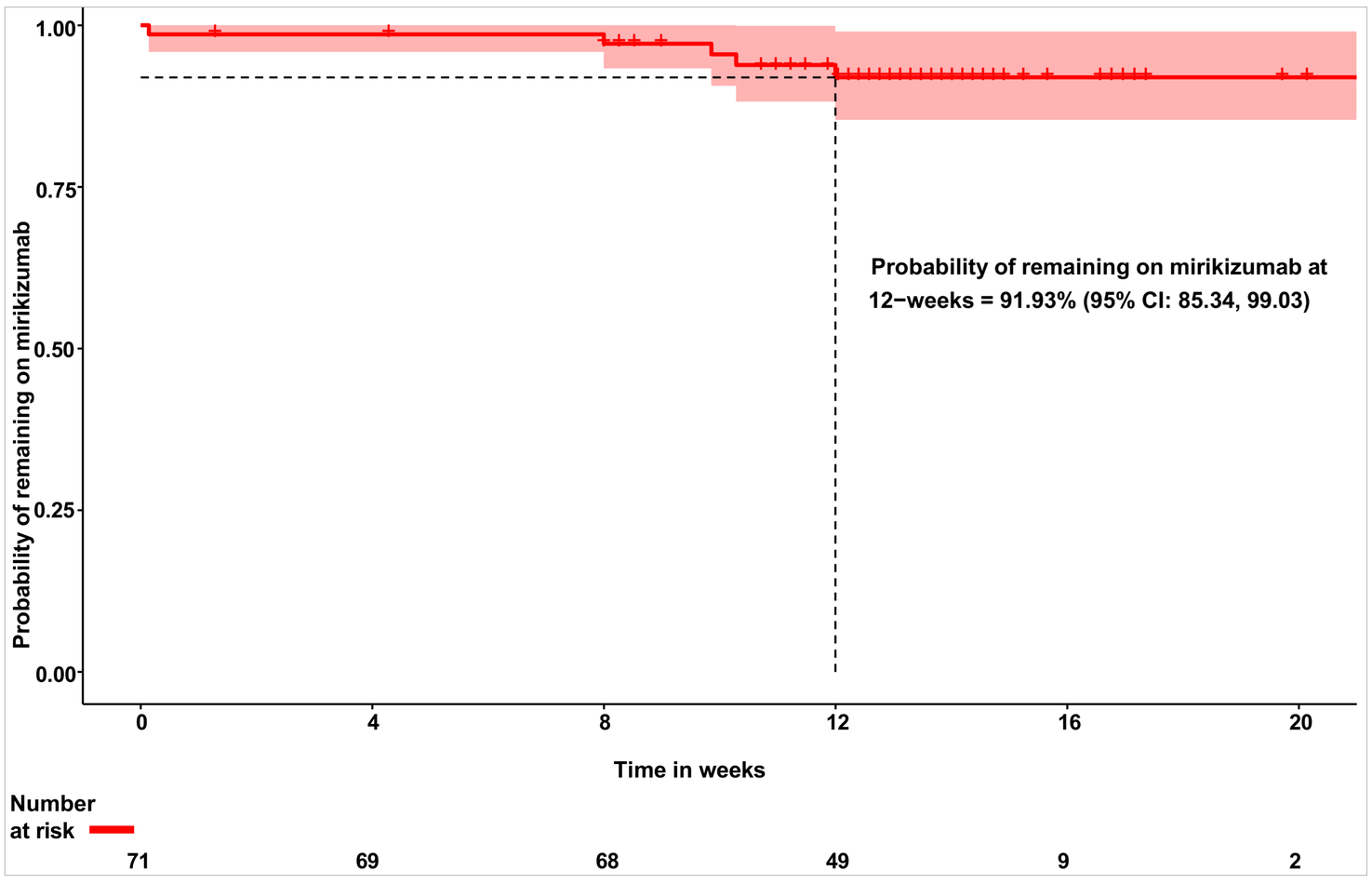
| Category | Variable | N=78 |
|---|---|---|
| Patient Demographics | **Age[d], n (%)** | |
| | 18–29 | 11 (14.1) |
| | 30–39 | 16 (20.5) |
| | 40–49 | 14 (18.0) |
| | 50–59 | 10 (12.8) |
| | 60–69 | 19 (24.4) |
| | ≥70 | 8 (10.3) |
| | **Female, n (%)** | 32 (41.0) |
| Clinical Characteristics | **Disease duration[d] (years), mean (SD)** | 9.97 (8.3) |
| | **Montreal classification, n (%)** | |
| | E1: Ulcerative proctitis | 6 (7.7) |
| | E2: Left sided ulcerative colitis | 31 (39.7) |
| | E3: Extensive ulcerative colitis | 32 (41.0) |
| | No data available | 9 (11.5) |
| | **Modified Mayo score[e], n (%)** | |
| | <4: Mild disease | 10 (12.8) |
| | 4–6: Moderate disease | 26 (33.3) |
| | 7–9: Severe disease | 19 (24.4) |
| | No data available | 23 (29.5) |
| | **Mayo – Mucosal endoscopic subscore[f], n (%)** | |
| | 2: Moderate | 21 (26.9) |
| | 3: Severe | 23 (29.5) |
| | No data available | 23 (29.5) |
| | **SCCAI – Urgency of defecation, n (%)** | |
| | 0: No urgency | 8 (10.3 |
| | 1: Hurry | 28 (35.9) |
| | 2: Immediately | 23 (29.5) |
| | 3: Incontinence | 11 (14.1) |
| | No data available | 8 (10.3) |
| | **CRP (mg/L), median (IQR)** | 4 (5.0) |
| | No data available, n (%) | 13 (16.7) |
| | **FCP (µg/mg), median (IQR)** | 813.0 (1,069.0) |
| | No data available, n (%) | 25 (32.1) |
| Prior and Concomitant UC Medications | **Prior treatment with an immunomodulator, n (%)** | 49 (62.8) |
| | **Prior treatment with any advanced therapy, n (%)** | 67 (85.9) |
| | 1 advanced therapy | 21 (26.9) |
| | 2 advanced therapies | 18 (23.1) |
| | 3+ advanced therapies | 28 (35.9) |
| | **Current treatment with an immunomodulator, n (%)** | 9 (11.5) |
| | **Current treatment with an oral steroid, n (%)** | 36 (46.2) |

**Abbreviations:** CRP, C-reactive protein; FCP, faecal calprotectin; IQR, interquartile range; %, percent; SD, standard deviation; SCCAI, Simple Clinical Colitis Activity Index. **Notes:** [b]Includes infliximab, adalimumab and golimumab; [c]Includes filgotinib, tofacitinib and upadacitinib; [d]Age and disease duration are approximates based on available data. Age bands are set by the data environment owner; [e]Modified Mayo score is the sum of the stool frequency, rectal bleeding and mucosal appearance at endoscopy subscore; [f]For Mayo – Mucosal endoscopic subscore, small patient counts were reported for 0: Normal or inactive disease (<5) and 1: Mild (<10). (Mayo Score - Copyright Mayo Clinic).

## Treatment Persistence

- At week 12, treatment persistence was 92%. Reasons for discontinuation[g] included adverse events, primary non-response, or withdrawal for other[h] reasons.

**Figure 1: Kaplan−Meier plot for Time−to−Treatment Discontinuation (N=71[a])**




**Abbreviations:** CI; confidence interval. **Notes:** [g]Discontinuation may reflect a true discontinuation or a treatment interruption (allowed up to 16 weeks per study protocol). Due the present level of follow-up available, it was not possible to determine at this stage; [h]Other' included reasons such as, but not limited to, withdrawal for surgery.

**Notes**: [a]7patients from the initially eligible cohort of 78 patients were excluded from this analysis due to missing or implausible follow-up data. **Abbreviations:** JAKi, Janus kinase inhibitor; IBD, inflammatory bowel disease; IgG4, immunoglobulin G4; IL-23p19, interleukin 23 subunit p-19; IV, intravenous; NHS, national health service in England; NIHR, national institute for health and care research; Q4W, every 4 weeks; SC, subcutaneous; TNFi, tumour necrosis factor inhibitor; UK, United Kingdom. **References:** 1. D'Haens et al. *N Engl J Med*. 2023; 2. Sands et al. *Inflamm Bowel Dis*. 2025; 3. Sands et al. *Inflamm Bowel Dis*. 2024; 4. Takagi et al. *Aliment Pharmacol Ther*. 2025; 5. St-Pierre et al. *Dig Dis Sci*. 2025; 6. Irving et al. *DDW ePoster*. 2025. **Disclosures**: P. Irving has received grants and/or research support from: Pfizer, Celltrion, Galapagos and Takeda; has been a consultant for: Sandoz, AbbVie, Takeda, BMS, Pfizer, Eli Lilly and Company, Celltrion and Alfasigma; C. S Casey, L. von Arx, E. Dhesi, B. Gittens are employees and minor shareholders of Eli Lilly and Company; R. Piper, A. Willis, M. Mirchandani are employees of Costello Medical and consultants of Eli Lilly and Company; L. Pele and M. Parkes have received contracts from: Eli Lilly and Company; T. Ahmad and M.T. Sharip declare no competing interests. **Acknowledgments:** We thank NIHR BioResource volunteers for their participation, and gratefully acknowledge NIHR BioResource centres, NHS Trusts and staff for their contribution. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. The authors would like to thank John Downey, PhD, and Philiswa Mbandlwa, PhD, for project management support and strategic scientific communication expertise.