Long-Term Health Outcomes in Patients With Moderate-to-Severe Ulcerative Colitis Treated With Guselkumab: A Model-Based Projection

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Background

Ulcerative colitis (UC) is characterized by relapsing and remitting mucosal inflammation in the colon and rectum that leads to the highly bothersome symptoms of rectal bleeding, abdominal pain, and diarrhea[1-3]

Treatment goals for patients with UC are to induce and maintain clinical remission, promote mucosal healing, and avoid or delay the need for surgery[1,3,4]

Treatment options for UC vary based on disease severity and include corticosteroids, immunomodulators, and advanced treatments (ADT) like tumor necrosis factor (TNF) antagonists, Janus kinase (JAK) inhibitors, and interleukin (IL)-12/23 and IL-23 antagonists[4]

Despite the availability of these therapies, long-term disease control remains challenging, with frequent treatment switching and suboptimal adherence to treatment contributing to high clinical and economic burdens[5-9]

Guselkumab, a dual-acting IL-23p19 subunit inhibitor,[10] may provide an option to address the challenges of long-term disease control in patients with UC

Objective

This study modeled long-term health outcomes in patients with moderate-to-severe UC who were treated with guselkumab by response to prior ADT (ie, response/tolerance to biologics and JAK inhibitors)

Methods

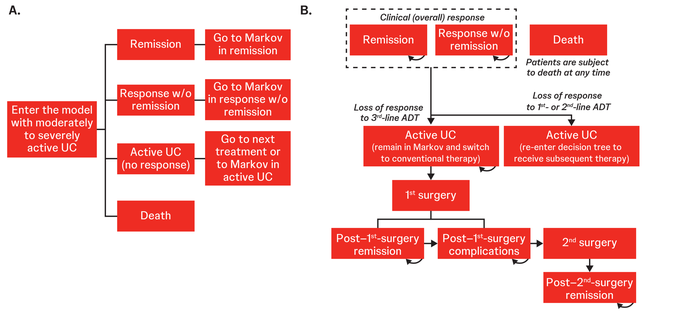
Model Structure

- A hybrid decision-analytical model, which combined a decision tree for induction and a Markov cohort model for maintenance, estimated clinical efficacy for adult patients treated with guselkumab who had prior inadequate response or intolerance to ADT (ADT-IR) and who did not have prior inadequate response or intolerance to ADT (non–ADT-IR)
  - The model assumed that 50% of patients received guselkumab 100 mg every 8 weeks and 50% received 200 mg every 4 weeks
- The induction phase decision tree adopted 4 distinct, mutually exclusive health states: remission, response without remission, active UC, and death. Patients entered the decision tree in active UC and were redistributed across health states at the end of the first cycle (**Figure 1A**)
- The maintenance phase included 9 distinct, mutually exclusive health states: response without remission, remission, active UC, first surgery, post–first-surgery remission, post–first-surgery complications, second surgery, post–second-surgery remission, and death. Patients continued to receive maintenance treatment if they remained in response with or without meeting remission criteria (**Figure 1B**)

Clinical Efficacy

- Clinical efficacy measures included time in remission; response; active UC; and surgery over 1, 3, and 5 years
- Efficacy in the induction phase was informed by a systematic literature review of randomized controlled trials in patients with moderate-to-severe UC
- In the maintenance phase, the probability of transitioning to conventional therapy for selected outcomes was derived from the QUASAR trial[11] and published literature

Figure 1. Decision tree schematics for the (A) induction therapy phase by model health state and (B) state-transition (Markov) model schematic for the maintenance therapy phase



*ADT=Advanced treatment, **UC**=Ulcerative colitis, **w/o**=Without.*

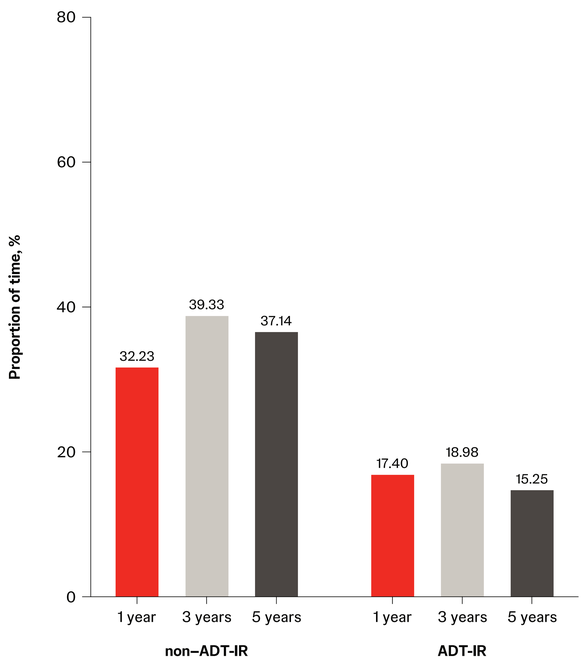
Key Takeaways

- **The model predicted that patients with non–ADT-IR who are treated with guselkumab will spend a greater proportion of time in remission and response and less time in active UC over 1, 3, and 5 years compared with patients with ADT-IR**
- **Consequently, the non–ADT-IR population would maintain the benefits of clinical remission and response for a longer period of time**
- **Reduced time in active disease states may lead to lower health care resource utilization and improved quality of life**

Results

In the non–ADT-IR population, patients spent a numerically greater amount of time in remission compared with the ADT-IR population at 1, 3, and 5 year time horizons (Figure 2)

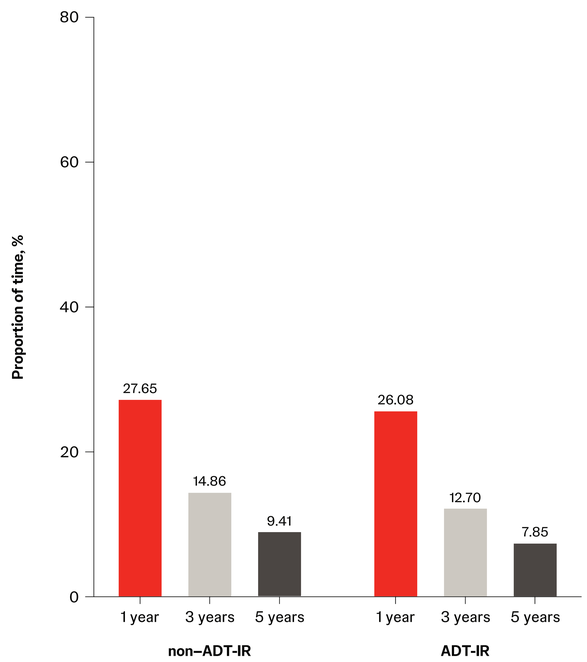
Figure 2. Time in remission



*ADT=Advanced treatment, **(non–)ADT-IR**=(No) prior inadequate response or intolerance to ADT.*

Time in the response state was numerically greater in the non–ADT-IR population compared with the ADT-IR population at 1, 3, and 5 year time horizons (Figure 3)

Figure 3. Time in response



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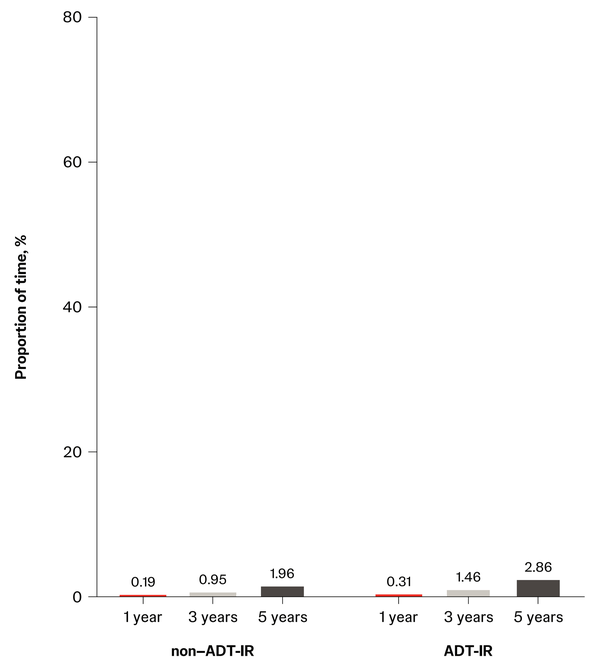
UC-related surgery time was low in both groups across all time horizons (Figure 4)

Figure 4. UC-related surgery time



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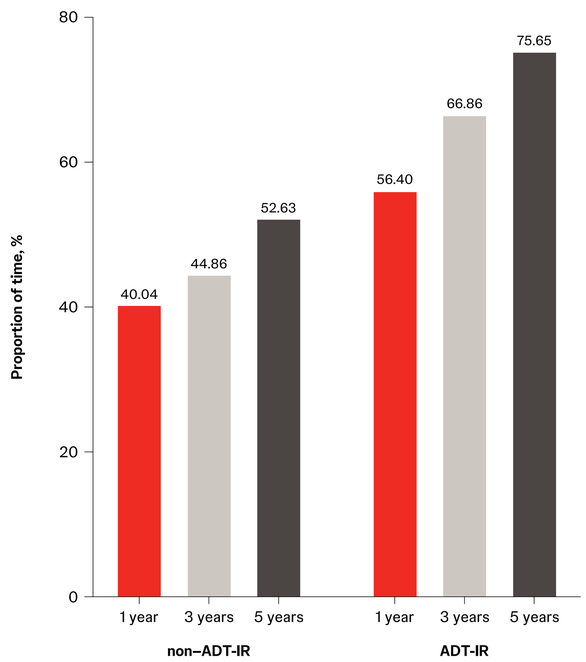
The ADT-IR population spent a numerically greater amount of time in active UC compared with the non–ADT-IR population across all time horizons (Figure 5)

Figure 5. Time in active UC



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