Long-Term Safety and Efficacy of Adalimumab in Patients with Noninfectious Intermediate Uveitis, Posterior Uveitis, or Panuveitis

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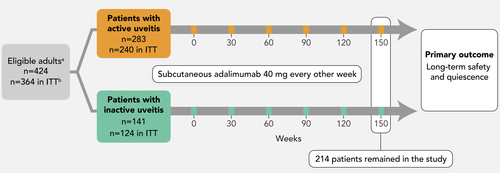
Noninfectious uveitis is one of the most common causes of vision loss or blindness in many population-based studies, and recurrent inflammation in patients with uveitis leads to potentially sight-threatening ocular complications. Given that corticosteroid treatment of inflammation can also cause potentially serious systemic and ocular toxicity, biologic therapies may provide effective steroid-sparing treatment of uveitis.

Adalimumab (Humira; AbbVie, Inc) is a human monoclonal antibody to tumor necrosis factor-α approved to treat noninfectious uveitis. The VISUAL I and II studies were phase 3 randomized clinical trials of adalimumab efficacy and safety to treat active or inactive uveitis, respectively. This study, VISUAL III, is an extension study of the VISUAL I and II trials that evaluated long-term efficacy and safety of extended treatment with adalimumab in patients with noninfectious intermediate uveitis, posterior uveitis, or panuveitis.

VISUAL III was an open-label, multicenter, phase 3 extension study of the VISUAL I and II studies that evaluated long-term efficacy and safety of extended treatment with adalimumab in patients with noninfectious uveitis.

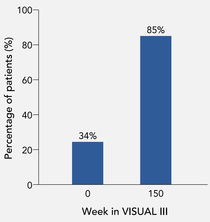


[a] Adults with noninfectious intermediate uveitis, posterior uveitis, or panuveitis could enroll in the VISUAL III study if they had successfully completed the VISUAL I or II studies without treatment failure (inactive uveitis) or discontinued the parent study having met treatment failure criteria (active uveitis).
[b] ITT = Intention to treat; 60 patients met exclusion criteria.

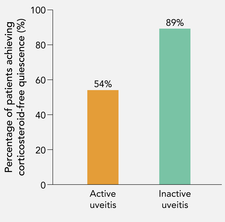
- Patients with active disease at study entry could receive concomitant corticosteroid therapy, immunosuppressive therapy, or both as permitted in the parent study.
- All patients were permitted to continue, taper, or discontinue concomitant corticosteroid therapy, immunosuppressive therapy, or both at investigator discretion.

Both active and inactive groups showed corticosteroid-free quiescence.

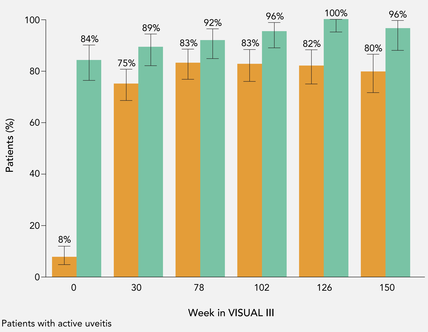
There was an increase in patients showing quiescence from baseline to week 150



Corticosteroid-free quiescence was achieved by both active and inactive uveitis patients



Percentage of patients achieving quiescence stratified by disease activity at baseline

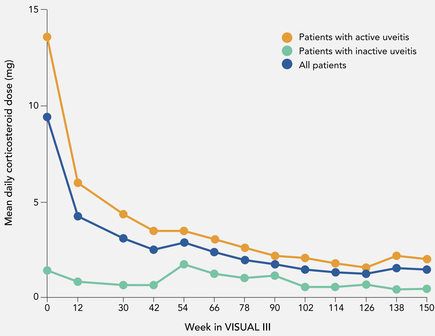


Data are presented as percentage ± exact 95% Clopper-Pearson confidence interval.

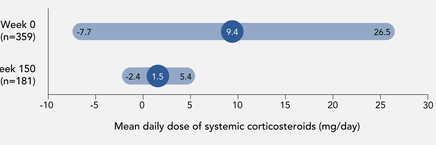
- Aside from quiescence, other efficacy variables included inflammatory lesions, anterior chamber cell and vitreous haze grade, macular edema, visual acuity, and dose of uveitis-related systemic corticosteroids.
- The percentage of patients who achieved other efficacy variables increased over time for those with active uveitis at study entry and was maintained for those with inactive uveitis.

There was an overall reduction in daily dose of systemic corticosteroids.

Mean daily dose of uveitis-related systemic corticosteroids

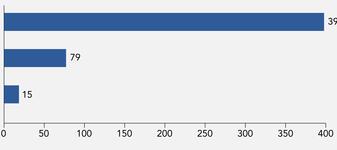


Reduction in mean daily dose of systemic corticosteroids



The types and incidence rates of adverse events (AEs) were similar to those reported for adalimumab in the parent trials and in studies of adalimumab for other approved indications.

Reported treatment-emergent adverse event rates in the VISUAL III study



Conclusions

Long-term treatment with adalimumab led to quiescence and reduced corticosteroid use for patients who entered VISUAL III with active uveitis, and led to maintenance of quiescence for those with inactive uveitis. AEs were comparable with those reported in the parent trials and consistent with the known safety profile of adalimumab.