These results suggest that maintenance of remission was defined as being in remission for 2 or more consecutive time points. The more stringent Boolean definition included patients who remained on therapy for 3 or more consecutive time points.

During maintenance of remission, approximately one third, i.e. 37.5% and 29.2%, of patients whose originally assigned ALX-0061 dose remained unmodified. The safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of ALX-0061 was assessed during a Phase I/II study in patients with active RA on stable MTX therapy [1].

The quality of normal physical function in patients with or without remission at week 24 is a registered trademark of Ablynx nv.

Background: ALX-0061: IL-6R targeting Nanobody

Methods (cont’d)

- Data were obtained from the multi-center, randomized, double-blind, placebo (PBO) controlled, dose escalation, Phase I/II study [1].
- During the first 12 weeks of the multiple ascending dose period, 37 patients received PBO (n=8) or ALX-0061 IV (n=29) at 1 or 3 mg/kg Q4W or 6 mg/kg Q8W. Patients received stable doses of MTX ranging from 10-25 mg/week.
- In the second 12 weeks period, patients with insufficient EULAR response had the ALX-0061 dose increased or switched from PBO to ALX-0061. 24 patients continued on their originally-assigned ALX-0061 IV dose (8 patients in 1 mg/kg arm, 8 patients in 3 mg/kg arm, and 8 patients in 6 mg/kg arm), 4 patients changed their dosing regimen, and 3 patients switched from PBO to ALX-0061.

- This post-hoc analysis utilized data from patients whose originally assigned ALX-0061 dose remained unmodified.

- The safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of ALX-0061 was assessed in a Phase I/I study in patients with active RA on stable MTX therapy [1].

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Results

- More patients in DAS28<2.6 remission at week 24 achieved normal physical function (86.7% vs. 22.2%) compared to patients not in remission.
- Moreover, normal physical function was observed in 100% (7/7) of patients in Boolean remission at week 24.

Conclusions

- This post-hoc analysis showed that in patients with established RA who remained on their originally assigned ALX-0061 dose, ALX-0061 induced and maintained remission as assessed both by DAS28<2.6 and the more stringent Boolean definition.

- Maintenance of remission during the last 3 (at weeks 16, 20, and 24) and last 4 (at weeks 12, 16, 20, and 24) consecutive time points is possible.

- Control of disease activity, as determined by remission, is also important in regaining normal physical function.

- These results suggest that ALX-0061 has the potential to be a disease modifying treatment supporting treat-to-target management of RA as reflected in the EULAR recommendations.

References


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