Results of a Phase IIb Study of Vobarilizumab, an Anti-Interleukin 6 Receptor Nanobody®, in Patients with Moderate-to-Severe Rheumatoid Arthritis despite Treatment with Methotrexate

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Ablynx’s Nanobodies®
Heavy and light chains
monovalent interaction
ACR50 and ACR70 responses of up to 45% and 21% were achieved (placebo 28% and 9%).

Early discontinuation
At Adverse events
Patients who completed the study could enroll in a 2-year openlife extension study.

Demographics and baseline disease characteristics were similar across groups, with mean age 53 years, 61% female, disease duration 9 years, DAS28 (28 joints) 5.8 (0.9) and CRP 6.2 (0.9). Early discontinuation was mandatory for patients with ≤20% improvement in both TC and SJC from baseline to discontinue from the trial but remained blinded to study drug assignment.

Background: vobarilizumab, an IL-6 receptor Nanobody®, in patients with moderate-to-severe RA despite treatment with methotrexate (MTX).

Methods

- This 24-week double-blind randomised controlled global trial, patients were randomized 1:1:1:1 to either subcutaneously administered placebo or one of 4 dose regimens of vobarilizumab in addition to MTX.
- The primary endpoint was the proportion achieving an ACR20 response at Week 12.

- The secondary endpoints included assessments of higher levels of ACR response and disease activity (DAS28), tolerability of treatment and serious adverse events.

- A large placebo effect was observed and is under investigation.

The results support the advancement of vobarilizumab into a phase III trial.