Two-year safety data for ABP 501 in patients with moderate to severe rheumatoid arthritis

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Background: Biosimilars are expected to have similar long-term safety profiles as originator products.

Objectives: To describe the consolidated, 2-year safety data on ABP 501, an approved biosimilar to adalimumab.

Methods: We combined individual patient data from a 26-week randomized controlled head-to-head study (parent study) comparing ABP 501 with adalimumab (NCT01970475) and its 72-week open-label extension (OLE) study (NCT02114931) in which all patients received only ABP 501. Safety data were reported by exposure-adjusted incidence rate as the number of subjects with the specified adverse events (AEs) per 100 person-years. AEs from the parent and OLE studies were summarized; for each category, patients were included only once based on the 1st event in that AE category. All comparisons were performed descriptively.

Results: In the parent study, 264 patients received ABP 501 and 262 patients received adalimumab reference product (RP). Of these, 229 in the ABP 501 arm and 237 in the RP arm entered and were treated in the open-label extension study. The exposure-adjusted incidence rate for treatment-emergent AEs by treatment group are shown in the Table.

Conclusions: Over the 2-year observation period, there were no meaningful differences in AEs between adalimumab reference product and ABP 501.