A total of 50 patients were enrolled, of whom 48 patients were randomly assigned at Week 6 into 4 cohorts (1:1:1:1 ratio). The mean trough (pre-dose serum concentration of CT-P13 before next dose injection) of SC cohorts throughout the study visits were higher than those of IV cohort at Week 6. The IV cohort received CT-P13 IV 3 mg/kg every 8 weeks and the SC cohorts received CT-P13 SC 90 mg, 120 mg or 180 mg, respectively, every 2 weeks up to Week 54. Pharmacokinetics blood samples were collected before study drug administration at each visit and drug levels were determined by electrochemiluminescent assay. Efficacy parameters including DAS28 and ACR criteria and overall safety were evaluated.

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Conclusion: The results from 1-year treatment suggest similar efficacy and safety of CT-P13 SC to CT-P13 IV in RA. The mean serum concentration in all SC cohorts consistently exceeded the threshold of target therapeutic concentration. These results show that the novel SC formulation of CT-P13 may enhance treatment options for use of infliximab biosimilar by providing high consistency in drug exposure.

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Background: Efficacy and safety of a new subcutaneous (SC) formulation (CT-P13 SC) up to Week 30 were comparable with intravenous (IV) formulation (CT-P13 IV) in both patients with rheumatoid arthritis (RA) [1] and Crohn’s disease [2].

Objectives: This report is to further investigate pharmacokinetics, efficacy and overall safety of CT-P13 SC in patients with RA throughout the 1-year treatment period.

Methods: Patients with active RA (presence of 6 or more swollen and tender joints [of 28 assessed], and serum C-reactive protein [CRP] concentration >0.6 mg/dL) were treated with CT-P13 IV at Weeks 0 and 2, and were randomized for continuation with CT-P13 IV or SC administration at Week 6. The IV cohort received CT-P13 IV 3 mg/kg every 8 weeks and the SC cohorts received CT-P13 SC 90 mg, 120 mg or 180 mg, respectively, every 2 weeks up to Week 54. Pharmacokinetics blood samples were collected before study drug administration at each visit and drug levels were determined by electrochemiluminescent assay. Efficacy parameters including DAS28 and ACR criteria and overall safety were evaluated.

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