ACR Convergence 2022

12S142. Abstracts: Spondyloarthritis Including PsA – Treatment I: Axial Spondyloarthritis (0542–0547)

0545. Continuing (Full or Reduced Treatment) versus Withdrawing from Golimumab in patients with non-radiographic axial spondyloarthritis who Achieved Inactive Disease: Efficacy and Safety Results from a Placebo-controlled, Randomized Withdrawal and Retreatment Study (GO BACK). (Clinical Trial no. NCT03253796)

Presented by Cindy Weinstein, Merck & Co. Inc.

Golimumab (GLM) is a TNFi, brand name Simponi. GO-Back is a current Phase IV trial, the first to examine the safety and efficacy of continued GLM treatment (full or reduced dosing frequency) compared with withdrawal (placebo) in patients who have achieved sustained inactive disease, and to assess the impact of GLM after a disease flare.

The primary endpoint of the study was the proportion of participants without a disease flare on continued GLM treatment versus GLM withdrawal during up to 12 months in Period 2 of the study. This was based on the hypothesis that continued GLM treatment would be superior to treatment withdrawal.

The conclusions were that among participants with active nr-axSpA who attained inactive disease after 10 months on GLM, continued treatment with GLM (either in full treatment monthly or reduced treatment every two months) was superior in preventing disease flares compared to placebo/full-treatment withdrawal; that monthly maintenance treatment was most beneficial at reducing the incidence of disease flares as well as the clinical signs and symptoms of nr-axSpA compared with treatment withdrawal or dose reduction; and that reattainment of clinical response after retreatment with GLM (full monthly dosing) for a disease flare was achievable for most participants (although fewer patients were able to sustain the response for three months.

GLM was also shown to be generally safe and well-tolerated, with a comparable incidence of adverse events across the treatment groups, findings that were consistent with the known safety profile of GLM.