Anifrolumab reduces disease activity in multiple organ domains in patients with moderate to severe systemic lupus erythematosus

Background Anifrolumab was evaluated in a Phase IIb study of adults with moderate to severe systemic lupus erythematosus (SLE), in which 305 patients received intravenous infusions of anifrolumab (300 mg, 1000 mg) or placebo for 48 weeks. Global disease activity was reduced in both dose groups compared with placebo, although a more favourable risk-benefit profile was observed with the 300-mg dose. This analysis of the Phase IIb study compared the impact of anifrolumab on individual organ domain activity at Day 365.

Materials and methods Changes from baseline in organ domain activity were assessed at Week 52 using the SLE Disease Activity Index 2000 (SLEDAI-2K) and British Isles Lupus Assessment Group (BILAG). SLEDAI domain improvement required a lower score compared with baseline in at least one of its components. BILAG organ domain improvement was defined as the transitioning from “A” or “B” to a lower score.

Results The majority of patients had baseline involvement of the mucocutaneous and/or musculoskeletal domains of SLEDAI-2K and BILAG. A greater percentage of anifrolumab-treated patients demonstrated improvement in these frequently involved domains compared with placebo (Table 1). Potential benefits were observed in most of the other less frequently active domains, including SLEDAI-2K cardiorespiratory, vascular, haematological, and constitutional; and BILAG cardiorespiratory and constitutional domains. In patients with baseline involvement in the SLEDAI-2K immunological domain (positive anti–double-stranded DNA [anti-dsDNA] and/or low complement level), normalisation of anti-dsDNA and/or hypocomplementemia were seen more frequently at Day 365 in patients receiving anifrolumab compared with placebo (Table 1).

However, among patients who had a normal anti-dsDNA and/or normal complements at baseline, a slightly greater number of patients in the 300-mg anifrolumab group had an increase in the score representing the development of a new anti-dsDNA or hypocomplementemia compared with baseline (Table 1).

Conclusions Treatment with anifrolumab resulted in greater rates of improvement in multiple organ domains compared with placebo. The greatest impact was seen with 300-mg anifrolumab.