Practical experience with XELJANZ® (tofacitinib) in ulcerative colitis

Satellite Symposium
Wednesday February 20, 2019
Timing: 17:00 – 17:45

XXXIst BWGE -2019
Hilton Hotel Antwerp
Room BIRD - Lijn

Speaker
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Cases of opportunistic infections have been reported (see section 4.4 of the SPC).

Serious infections

Phase 2/3 induction studies, the proportions of patients with infections were 21.1% (198 patients) in the tofacitinib 5 mg twice daily arm only, 20.9% (194 patients) in the tofacitinib 10 mg twice daily arm only and 20.7% (192 patients) in the placebo group (total 559 patients). In the randomised 52-week Phase 3 maintenance study, the proportion of patients with infections was 16.8% (91 patients) in the placebo plus MTX group and 20.4% (114 patients) in the tofacitinib 5 mg twice daily group (total 507 patients) and 17.1% (103 patients) in the placebo plus DMARD group (total 559 patients). The most commonly reported infections were upper respiratory tract infections, nasopharyngitis, cellulitis, sinusitis, pneumonia, and urinary tract infections. The incidence rate of infections with tofacitinib in the long-term safety all studies was 15.2% (679 patients) for tofacitinib 5 mg twice daily, 19.6% (675 patients) for tofacitinib 10 mg twice daily, and 11.8% (663 patients) for placebo. Nineteen patients treated with tofacitinib had serious infections (see section 4.4 of the SPC). The most common serious infections were serious infections (see section 4.4 of the SPC).

Overall infections

In an RA controlled clinical trial, elevations in LDL cholesterol and ApoB decreased to pretreatment levels in response to tofacitinib. However, elevations in the lipid parameters remained consistent with what was seen in the controlled clinical studies. In long-term studies, the lipid parameters over 2 years were as follows: in the placebo group, LDL cholesterol increased by 22% at month 24 (7.8% increase at month 12) and increased by 21% in the tofacitinib 5 mg twice daily group at month 12; Mean HDL cholesterol increased by 17% in the placebo group at month 24 and increased by 19% in the tofacitinib 5 mg twice daily group at month 12, and increased by 18% in the tofacitinib 10 mg twice daily group at month 12.

The ALT elevations observed in the placebo group were generally consistent with the population background. The prevalence of ALT elevations greater than 3x ULN at the end of the study (6-24 months) in the controlled clinical studies in RA are summarised below: Mean LDL cholesterol increased by 15% in the tofacitinib 5 mg twice daily group and 20% in the tofacitinib 10 mg twice daily group at month 12, and increased by 16% in the tofacitinib 5 mg twice daily group and 19% in the tofacitinib 10 mg twice daily group at month 24. Mean HDL cholesterol increased by 15% in the tofacitinib 5 mg twice daily group and 13% in the tofacitinib 10 mg twice daily group at month 12, and increased by 19% in the tofacitinib 5 mg twice daily group and 20% in the tofacitinib 10 mg twice daily group at month 24. Upon withdrawal of tofacitinib treatment, lipid levels returned to baseline. Mean LDL cholesterol/HDL cholesterol ratio and ApoA1/HDL ApoA1 ratio were essentially unchanged in tofacitinib-treated patients.

In the long-term extension studies, on-treatment ALT elevations over 6 months were generally consistent with what was observed in the controlled clinical studies. In the long-term extension studies, the ALT elevations observed in the placebo group were generally consistent with the population background. The prevalence of ALT elevations greater than 3x ULN at the end of the study (6-24 months) in the controlled clinical studies in RA are summarised below: Mean LDL cholesterol increased by 15% in the tofacitinib 5 mg twice daily group and 20% in the tofacitinib 10 mg twice daily group at month 12, and increased by 16% in the tofacitinib 5 mg twice daily group and 19% in the tofacitinib 10 mg twice daily group at month 24. Mean HDL cholesterol increased by 15% in the tofacitinib 5 mg twice daily group and 13% in the tofacitinib 10 mg twice daily group at month 12, and increased by 19% in the tofacitinib 5 mg twice daily group and 20% in the tofacitinib 10 mg twice daily group at month 24. Upon withdrawal of tofacitinib treatment, lipid levels returned to baseline. Mean LDL cholesterol/HDL cholesterol ratio and ApoA1/HDL ApoA1 ratio were essentially unchanged in tofacitinib-treated patients.

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