Fatigue results from ASPIRE (from Zeuzem and colleagues[10])

At baseline the FSS scores in the simeprevir + PR and placebo + PR groups were approximately 1 point higher than the established normative value for healthy adults. Zeuzem and colleagues[10] reported narratively that in all study groups the mean FSS score increased from baseline to week 12, remained stable to week 48, and returned to values at or below baseline by weeks 70-72. There were no clinically or statistically significant differences between study groups during the 72-week study period.

Adverse events in ASPIRE (from MS and Zeuzem and colleagues[10])

One death (due to bacterial meningitis) occurred and this was in the simeprevir + PR group, but was not deemed related to the simeprevir treatment. The incidence of adverse events was generally comparable between the study groups, although pruritus and neutropenia were ≥10% more frequent in the simeprevir + PR group (pruritus 30.3% vs 16.7%; neutropenia 27.3% vs 16.7%).[10] The only clinically significant change in laboratory parameters was hyperbilirubinaemia which occurred in all treatment groups during the first 2 weeks, with bilirubin levels subsequently returning to baseline values or below by week 52.