Patients enrolled:
n = 307
Not randomised: n = 4
• Did not meet inclusion criteria: n = 2
• Adverse event[a]: n = 1
• Withdrawal of consent: n = 1
Patients randomised:
n = 303
Not treated: n = 0
Patients treated:
n = 303
Placebo:
n = 151
Ozanezumab:
n = 152
Completed placebo[b]:
n = 115
Withdrew from placebo:
n = 36
Completed ozanezumab[b]:
n = 106
Withdrew from ozanezumab:
n = 46
Withdrew from study:
n = 7
Withdrew from study:
n = 34
Withdrew from study:
n = 6
Withdrew from study:
n = 40
Completed study:
n = 108
Provided data to Week 48[c]
n = 2
Completed study:
n = 100
Provided data to Week 48[c]:
n = 6
Reasons for withdrawal from study
Adverse Event: n = 17 (11%)
Lack of efficacy: n = 3 (2%)
Stopping criteria reached: n = 1 (<1%)
Lost to follow-up: n = 2 (1%)
Physician decision: n = 4 (3%)
Withdrawal of consent: n = 14 (9%)
Reasons for withdrawal from study
Adverse Event: n = 18 (12%)
Lack of efficacy: n = 1 (<1%)
Stopping criteria reached: n = 0
Lost to Follow-up: n = 1 (<1%)
Physician decision: n = 2 (1%)
Withdrawal of consent: n = 24 (16%)