Supplementary information

Sample size calculation

Sample size was determined based on three placebo-controlled studies with PD patients in Japan using UPDRS Part 3 total scores as the primary endpoint.\(^{1-3}\) The between-group difference with placebo (mean ± pooled SD) was -4.3 ± 7.7 and -3.0 ± 7.3 in the zonisamide 25 mg group, and -5.6 ± 9.9, -3.8 ± 7.1 and -2.6 ± 6.8 in the zonisamide 50 mg group. Therefore, the effect size in DLB patients was postulated to be 0.5 for both the zonisamide 25 and 50 mg groups. It was calculated that 59 patients per group were necessary for a significance level of 5% and power of 80%, but the target number of patients was determined to be 50 patients per group (detection power: 72%) in this study.
References

