ADJUNCTIVE ESLICARBAZEPINE ACETATE: A POOLED ANALYSIS OF THREE PHASE III TRIALS

Biton V, et al. *Epilepsy Behav* 2017;72:127–34

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OBJECTIVE

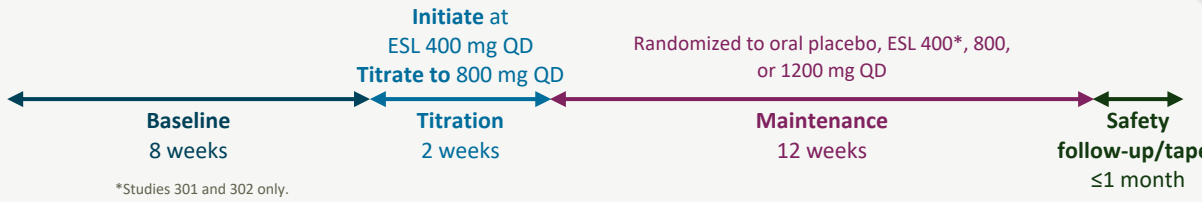
To assess the efficacy and safety of adjunctive ESL in adults with refractory focal seizures

STUDY DESIGN

Pooled data from Phase III clinical trials

Patients aged ≥16 years with focal seizures not adequately controlled with 1–3 ASMs

BIA-2093-301
BIA-2093-302
BIA-2093-304



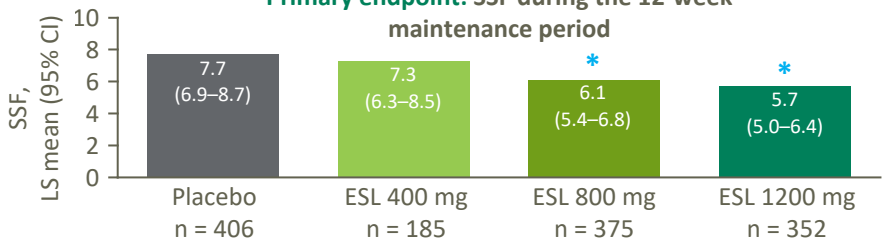
*Studies 301 and 302 only.

RESULTS

EFFICACY

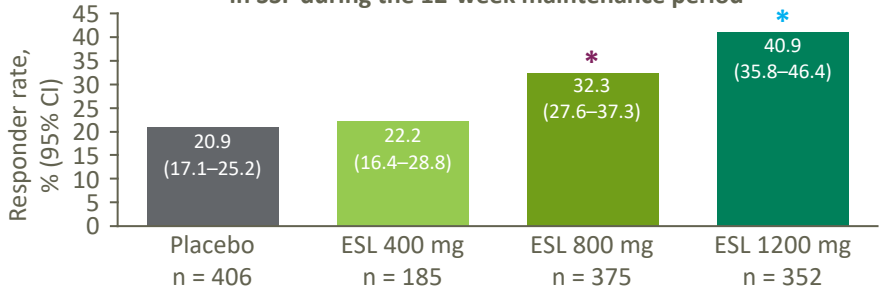
Primary endpoint: SSF during the 12-week maintenance period

↓ SSF = fewer seizures



Responder rate: Proportion of patients with ≥50% reduction in SSF during the 12-week maintenance period

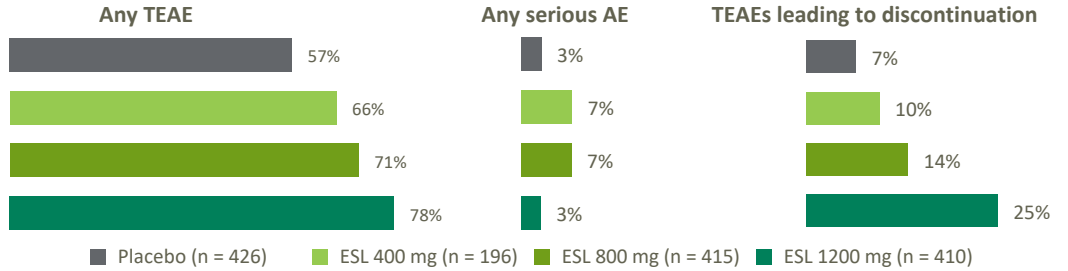
↑ Responder rate = fewer seizures



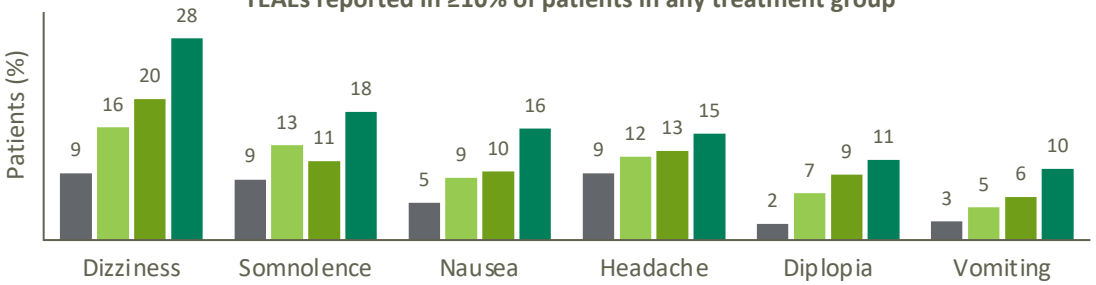
*Significantly different to placebo Blue asterisk: p≤0.0001 Purple asterisk: p=0.0003

There were no significant interactions between treatment effect and age, gender, race/ethnicity, geographic region, epilepsy duration, or concomitant ASM use

SAFETY



TEAEs reported in ≥10% of patients in any treatment group



Incidences of the most frequent TEAEs were lower for patients who initiated dosing at 400 versus 800 mg QD, regardless of titration regimen and maintenance dose

Three deaths were reported:

Placebo
2 patients
- Due to acute respiratory failure and possible SUDEP

ESL 800 mg
1 patient
- During titration period while taking ESL 400 mg, due to probable SUDEP

CONCLUSIONS

ESL (800 and 1200 mg QD) was effective and well tolerated as adjunctive therapy for adults with refractory focal seizures

Abbreviations: ASM, antiseizure medication; CI, confidence interval; ESL, eslicarbazepine acetate; LS, least squares; QD, once daily; SSF, standardized seizure frequency (seizures per 4 weeks); SUDEP, sudden unexpected death in epilepsy; TEAE, treatment-emergent adverse event.

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