(48/1216, 3.9%, and 16/1216, 1.3%, respectively). 227 patients (18.7%) had serious AEs (SAEs). The only individual SAEs in >1% of patients were epilepsy-related; others (in >5 patients) were aggression (n=12, 0.99%; 5 resolved, 7 withdrew), head injury (11, 0.90%), pneumonia (10, 0.82%), psychotic disorders (6, 0.49%), and suicidal ideation (6, 0.49%). Two patients died since previous cut-off (5 total; none study-drug-related). At 122 weeks, mean weight gain was 2.96 ± 6.6 Kg (N=200). No clinically relevant changes in vital signs, ECG parameters, or labs were seen.

Conclusions No new safety signals identified, with 7260 additional patient-months.

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074

LONG-TERM SAFETY OF PERAMPANEL: ADDITIONAL 10 MONTHS OF DATA FROM EXTENSION STUDY 307 IN PATIENTS WITH PARTIAL-ONSET SEIZURES AGED 12 AND ABOVE

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Purpose Extending perampanel long-term safety/tolerability data, with an additional 10 months (cut-off Oct 2011).

Methods Participants in study 307 (NCT00735397) had completed a Phase III perampanel trial, and were titrated to 12 mg/day (or individual maximum tolerated dose) during blinded titration, followed by open-label maintenance.

Results Of 1216 patients, 1122 (92.3%) reached 10 or 12 mg/day (mean maintenance dose 10.61 mg/day). Median exposure was 1.5 years (1 week–3.3 years), totalling 21635 patient-months. Treatment retention was 58.5% at cut-off. Subject choice or inadequate efficacy drove most discontinuations. AEs occurred in 1110 patients (91.3%); majority (80.2%) were mild/moderate. AEs seen in $\geq 10\%$ of patients were dizziness (46.8%), somnolence (21.2%), headache (18.3%), fatigue (13.1%), irritability (11.5%) and weight increase (10.9%). Only dizziness and irritability caused discontinuation in >1%