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LONG-TERM SEIZURE OUTCOMES WITH PERAMPANEL IN REFRACTORY PARTIAL-ONSET SEIZURES AND SECONDARILY GENERALISED PARTIAL SEIZURES: 10 MONTHS ADDITIONAL DATA FROM EXTENSION STUDY 307 FOLLOWING THREE PHASE III CLINICAL TRIALS

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Purpose Extending duration of analysis with up to two years perampanel exposure.

Methods We report 7260 additional patient-months (cut-off Oct 2011) from extension study 307 (NCT00735397). Seizure outcomes were analysed in 13-week intervals (time from first perampanel exposure) in patients with ≥6, 9, 12, and 24 months' exposure, allowing seizure outcomes to be examined over time without being confounded by changing patient numbers as the study progresses.

Results Of the 1216 intent-to-treat patients, 1090 (89.6%), 980 (80.6%), 874 (71.9%) and 337 (27.7%) had perampanel exposure of ≥6, 9, 12, and 24 months, respectively. Declining numbers reflected later start-dates and time of data cut-off, as well as drop-outs. Patterns of seizure outcomes were similar for median % change from baseline in seizure frequency, and responder rate (RR; % with ≥50% reduction) and between the four subsets based on treatment duration. Most improvements occurred during early weeks of exposure (RR=32–35% at week 1–13 and 42–48% at weeks 14–26). Seizure outcomes were stable across longer exposures: RR ranged from 52% (weeks 27–39) to 58% (weeks 92–104) in patients with ≥24 months of data. Patterns were similar in secondarily generalised seizures, where RR ranged from 64.7–67.4% at 27–39 weeks, to 73.0% at 92–104 weeks.

Conclusions Seizure outcomes with adjunctive perampanel, in refractory partial-onset seizures, are stable over time, with data up to 2 years.