066 **LONG-TERM SAFETY AND EFFICACY OF ZONISAMIDE VERSUS CARBAMAZEPINE MONOTHERAPY FOR TREATMENT OF PARTIAL SEIZURES IN ADULTS WITH NEWLY DIAGNOSED EPILEPSY: RESULTS OF A PHASE III, MULTINATIONAL, RANDOMISED, DOUBLE-BLIND, ACTIVE-CONTROLLED STUDY**

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Purpose To assess the long-term safety and efficacy of zonisamide versus carbamazepine monotherapy for partial seizures in adults with newly diagnosed epilepsy.

Method Adult patients completing a Phase III, randomised, double-blind, non-inferiority trial comparing zonisamide versus carbamazepine monotherapy entered a long-term extension study, continuing the same treatment (zonisamide, N=137; carbamazepine, N=158). Dose ranges were zonisamide 200–500 mg/day and carbamazepine 400–1200 mg/day. Safety assessments included treatment-emergent adverse events (TEAEs) and clinical laboratory parameters. Efficacy assessments included retention and seizure freedom rates.

Results Overall incidence of TEAEs was similar for zonisamide (52.6%) versus carbamazepine (46.2%). Most TEAEs (>95%) were of mild or moderate intensity; the most commonly reported being decreased weight (5.8% vs. 0%) and headache (4.4% vs. 6.3%). Incidences of serious treatment-related TEAEs and TEAEs leading to withdrawal were low and similar between groups (0.7% vs. 1.9% and 1.5% vs. 0.6%, respectively). There were small-to-moderate decreases in bicarbonate levels from baseline in the zonisamide group (mean -3.4 mmol/L). Vital signs and physical/neurological examinations identified no safety concerns. Retention rates for zonisamide versus carbamazepine were generally similar at all time-points (58.4% vs. 61.4%, 27.7% vs. 27.8% and 5.8% vs. 2.5% at 12, 18 and 24 months, respectively; intent-to-treat population). Seizure freedom rates after 24 months of treatment were 32.3% versus 35.2% (zonisamide vs. carbamazepine; intent-to-treat population).

Conclusion Zonisamide monotherapy demonstrated favourable long-term safety and maintenance of efficacy when used to treat partial seizures in adults with newly diagnosed epilepsy. No new or unexpected safety findings emerged.

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