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## CLINICAL DEVELOPMENT OF ESLICARBAZEPINE ACETATE FOR EPILEPSY

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**Background:** Eslicarbazepine acetate (ESL) is rapidly and extensively metabolized to its major active metabolite, eslicarbazepine which blocks voltage-gated sodium channels. Compared with carbamazepine, oxcarbazepine, and (R)-licarbazepine, studies have shown that the S-enantiomer, (eslicarbazepine) demonstrated greater binding selectivity for the inactive state over the resting state of the sodium channel.

**Description of Studies:** Phase 3 studies of once-daily (QD) adjunctive use for refractory partial onset seizures in adults were completed ex-US. Several clinical trials are currently underway and include: an additional phase 3 double-blind, randomized, adjunct trial in adults with partial onset seizures that includes US subjects; and two withdrawal to monotherapy studies using a historical control design in adults with partial onset seizures; and an active-control trial to test monotherapy in adults with newly diagnosed partial onset seizures. Pediatric trials are ongoing.

**Results and Conclusions:** In randomized trials in adults, adjunctive ESL 800 mg and 1200 mg QD demonstrated significantly greater reductions in seizure frequency compared to placebo, and were well tolerated. Long-term safety was demonstrated in open-label extensions of these studies. Ongoing studies are expected to confirm earlier findings and expand knowledge of the potential role of ESL in other areas of epilepsy treatment.

**Stage of Development:** Currently, ESL is not approved in the United States but is in phase 3, and approved as adjunctive treatment in adults with partial onset seizures with or without secondary generalization in Europe.

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