

## **Long term efficacy of Eslicarbazepine acetate (ESL): results from BIA-2093-311/EXT study - the 2 year open-label extension of the ESL monotherapy study (BIA-2093-311)**

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Introduction: Eslicarbazepine acetate (ESL) was approved by the European Medicines Agency as monotherapy treatment for newly diagnosed adults with focal seizures based on a phase III, randomized, double-blind (DB), active-controlled (controlled-release carbamazepine, CBZ-CR), non-inferiority study (Trinka et al., *Epilepsia*:59;479-491, 2018). The patients concluding the DB study were allowed to continue to a 2-year open-label extension (OL) study. The aim was to evaluate the response to ESL in long-term use. Material and methods: Patients previously treated with CBZ-CR (N= 97) in the DB study switched to ESL in the OL (CBZ-ESL), whilst those treated with ESL (N=109) continued with their last evaluated dose in the DB study, 800 mg, 1200 mg or 1600 mg QD (ESL-ESL). Efficacy was analyzed using incidence of treatment failure due to intolerable AE or lack of efficacy, seizure freedom, responder rate (at least 50 % reduction in seizure frequency compared DB baseline), and overall treatment satisfaction. Results: 172 (83.5%) of 206 patients entered the OL study completed the 2-year extension study. The majority of the ESL-ESL maintained the same ESL dose (92.7%), and 85.3% of 109 were seizure-free during the 2-year study. For CBZ-ESL, 12 (12.4%) of 97 increased the ESL dose during the OL study, with a seizure-freedom rate of 76.3% (74/97). Regarding the primary reason for discontinuation, only one subject (0.5%) discontinued due to lack of efficacy (inadequate seizure control), and 12 (5.8%) due to an adverse event. The responders at end of study visit (EOS) were 171 (83.0%) of 206. The treatment satisfaction was very good or good for 170 (98.8%) of 172 patients who completed the 2-year extension study, and for 171 (99.4%) of the investigators. Conclusions: The efficacy of ESL was sustained during long-term treatment of patients with focal epilepsy, supporting the potential use of ESL as long-term monotherapy.