

CLINICAL STUDY REPORT SYNOPSIS: N01125

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	
Title of study: An Open-Label, Multi-Center, Follow-up Trial to Evaluate Long-Term Safety and Efficacy of Brivaracetam (ucb 34714) Used as Adjunctive Treatment at a Flexible Dose up to a Maximum of 200mg/day in Subjects Aged 16 Years or Older Suffering from Epilepsy		
Investigator(s): [REDACTED] MD, PhD		
Study site(s): This study was conducted in 26 countries, including Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Hong Kong, Hungary, Israel, Italy, Netherlands, Norway, Poland, Russia, Serbia, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Tunisia, Ukraine, and the US. There were a total of 156 investigational sites.		
Publication(s) (reference[s]): Toledo M, Whitesides J, Schiemann J, Johnson ME, Eckhardt K, McDonough B, et al. Safety, tolerability, and seizure control during long-term treatment with adjunctive brivaracetam for partial-onset seizures. <i>Epilepsia</i> . 2016;57:1139-51.		
Study period: Approximately 13 years, 8.5 months		Phase of development: Phase 3
First study participant enrolled: 08 Sep 2005		
Last study participant completed: 28 May 2019		
<p>Objective(s): The primary objective was to evaluate the long-term safety and tolerability of brivaracetam (BRV) at individualized doses with a maximum of 200mg/day in study participants suffering from epilepsy.</p> <p>The secondary objective was to evaluate the maintenance of efficacy over time of BRV (for partial-onset seizure [POS]/ primary generalized seizures [PGS] study participants). No efficacy objectives were defined for study participants with Unverricht-Lundborg Disease (ULD) or participants entering the study from N01315.</p> <p>Exploratory objectives for POS/PGS study participants were: to explore direct medical resource use and indirect cost parameters for the first 2 years, to obtain a description of the study participant's self-reported health status for the first 2 years, to explore the effects of BRV on the study participant's Health-related Quality of Life, anxiety, and depression for the first 2 years, and to explore any change in the study participant's socioprofessional status for the first 2 years. No exploratory objectives were defined for ULD or N01315 study participants.</p>		

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	

Methodology: N01125 was a Phase 3, open-label, multicenter, LTFU study to evaluate long-term safety and efficacy of BRV used as adjunctive treatment at a flexible dose up to a maximum of 200mg/day in study participants aged 16 years or older diagnosed with epilepsy or ULD.

Study participants enrolled in N01125 and subpopulations were defined as follows:

- Participants with POS:
 - from the previous studies N01114, N01252, and N01315
 - from N01254 with a diagnosis of POS at N01254 study entry
- Participants with PGS:
 - from N01254 with a diagnosis of PGS at N01254 study entry
- Participants with ULD:
 - from the previous studies N01187 and N01236

The study ran throughout the duration of the clinical development period of BRV, and continued until a marketing authorization was granted by any Health Authority in an indication for the adjunctive treatment in adults with refractory POS, whether or not secondarily generalized, until the Sponsor decided to close the study, until a managed access program, named patient program, compassionate use program, or similar type of access program was established as allowed per country-specific requirement in addition to legal and regulatory guidelines, or until BRV development was stopped by the Sponsor.

The following study periods were defined:

- Evaluation Period (Visit 1/ Entry Visit [EV] until the Final Visit [FV] or Early Discontinuation Visit [EDV]). The EV was performed on the same day as the last visit of the previous study in which the participant was enrolled.
- Down-Titration Period
 - If the study participant was discontinuing study drug, the Investigator planned an EDV and the progressive down-titration of study drug.
 - During the Down-Titration Period, the BRV dose may have been decreased in steps of a maximum of 50mg/day on a weekly basis. A last down-titration step at 20mg/day for 1 week should have been included prior to the Post-Treatment Period.
 - Study participants who down-titrated from doses higher than 20mg/day had a Down-Titration Phone Call.
- Post-Treatment Period (2 to 4 weeks): After completion of the Down-Titration Period, the

<p>Name of company: UCB Pharma SA</p>	<p>Individual study table referring to part of the dossier: Not applicable</p>	<p><i>(For National Authority Use Only)</i></p>
<p>Name of finished product: Not applicable</p>	<p>Volume: Not applicable</p>	
<p>Name of active ingredient: Brivaracetam</p>	<p>Page: Not applicable</p>	
<p>study participant entered a Post-Treatment Period for a minimum of 2 weeks and a maximum of 4 weeks, followed by a FV.</p> <p>The end of the study was defined as the date of the last visit of the last study participant in the study.</p> <p>An abbreviated CSR based on a clinical cutoff date of 17 Jan 2014 was previously submitted for N01125 for the purpose of providing supportive information for the BRV POS adjunctive therapy New Drug Application (NDA)/Marketing Authorization Application (MAA). The current report is the final CSR based on the completed study.</p>		
<p>Number of study participants (planned and analyzed): The Safety Analysis Set (N=853 participants) consisted of all study participants (including POS, PGS, and ULD) who took at least 1 dose of study drug but not including study participants entering the study from N01315. A Modified Safety Analysis Set (N=859 participants) was also defined to consist of all study participants who took at least 1 dose of study drug including study participants entering the study from N01315. Efficacy Analysis Sets (POS and PGS) consisted of all study participants who took at least 1 dose of study drug and had at least 1 seizure DRC day during the Evaluation Period. Separate Efficacy Analysis Sets were defined for study participants with focal epilepsy from N01114, N01252, and N01254 (POS [N=729 participants]) and study participants with generalized epilepsy from N01254 (PGS [N=30 participants]).</p>		
<p>Diagnosis and main criteria for inclusion: This study enrolled male or female study participants with epilepsy aged 16 years or older who had been inpatients or outpatients with epilepsy who participated in previous BRV studies/programs that allowed access to the present study. N01125 gave study participants for whom the Investigator believed a reasonable potential benefit from the long-term administration of BRV was expected the opportunity to continue BRV treatment. Study participants with severe medical, neurological, and psychiatric disorders, including current suicidal ideation or behavior, or laboratory values which may have had an impact on the safety of the study participant, as determined by the Investigator, were excluded.</p>		
<p>Test product, dose(s) and mode of administration, batch number(s): For study participants coming from the Phase 2 study N01114, tablets or capsules were used. The study participants coming from N01114 who were receiving capsules were progressively switched to tablets. For study participants coming from Phase 3 POS/PGS studies, tablets were used. The 50mg tablet was not administered to study participants with POS or PGS; for study participants with ULD, the 50mg tablet was completely removed after Amendment 25. Prior to Amendment 26, 80- and 200-tablet containers were provided. The 80-tablet container was phased out after Amendment 25.</p>		

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	
<p>The batch numbers for the administered BRV are as follows:</p> <ul style="list-style-type: none"> For the 2.5mg strength, batch numbers were as follows: 2776.115, 2776.122, 2776.123, 202776/10, BX1001992, BX1002225, BX1002226, BX1002834, BX1002835, and BX1003499. For the 10mg strength, batch numbers were as follows: 15938, 239400, 254934, 202776/1, 202776/11, 202776/12, 202776/13, 202776/14, 202776/2, 202776/3, 202776/4, 2776.160/BX1006685, BX1002279, BX1002281, BX1002284, BX1002288, BX1002940, BX1002944, BX1002982, BX1002983, BX1003403, BX1003688, BX1003787, BX1003874, BX1003908, BX1008115, BX1010913, BX1011858, BX1012876, and BX1014305. For the 25mg strength, batch numbers were as follows: 2776.126, 14062, 14312, 14315, 14619, 14645, 14646, 14772, 14980, 15525, 234108, 244249, 254935, 202776/5, 202776/7, 202776/7@12, 202776/8, 202776/9, 2776.159/BX1006684, BX1002276, BX1002307, BX1002308, BX1003015, BX1003021, BX1003022, BX1003047, BX1004333, BX1008116, BX1008307, BX1010914, BX1010915, BX1011859, BX1012515, and BX1012877. For the 50mg strength, batch numbers were as follows: 13720, 13913, 13914, 14059, 14060, 14316, 14317, 14773, 14979, and 202776/6. 		
<p>Duration of treatment: For each study participant, the study ran throughout the duration of the clinical development period of BRV, and continued until a marketing authorization was granted by any Health Authority in an indication for the adjunctive treatment in adults with refractory POS, whether or not secondarily generalized, until the Sponsor decided to close the study, until a managed access program, named patient program, compassionate use program, or similar type of access program was established as allowed per country-specific requirement in addition to legal and regulatory guidelines, or until BRV development was stopped by the Sponsor.</p>		
<p>Reference therapy, dose(s) and mode of administration, batch number(s): None</p>		
<p>Criteria for evaluation:</p> <p>Safety: The primary safety variables of N01125 were as follows:</p> <ul style="list-style-type: none"> Occurrence of a treatment-emergent adverse event (TEAE) Withdrawal due to adverse event (AE) Occurrence of a serious AE (SAE) <p>Other safety variables included:</p> <ul style="list-style-type: none"> Laboratory tests (hematology, blood chemistry, urinalysis) 		

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	
<ul style="list-style-type: none"> • Vital signs (systolic blood pressure, diastolic blood pressure, pulse rate) and body weight • Electrocardiogram (ECG) • Physical and neurological examinations • Change in Hospital Anxiety and Depression Scale (HADS) scores from the Baseline of the previous study to each assessment for the first 2 years and to the last Evaluation Period assessment during the first 2 years 		
<p>Efficacy: The secondary variables of N01125 were as follows: For study participants with focal onset epilepsy:</p> <ul style="list-style-type: none"> • POS (T3as a study participant with a $\geq 50\%$ reduction in seizure frequency from the Baseline Period of the previous study. <p>No efficacy variables were defined for study participants with generalized epilepsy or study participants with ULD, or participants coming from N01315.</p> <p>The other efficacy variables of N01125 for study participants with focal onset epilepsy:</p> <ul style="list-style-type: none"> • Percentage of study participants continuously seizure free for all seizure Types (I+II+III) for at least 6 months and at least 12 months during the Evaluation Period. <p>The other efficacy variables of N01125 for study participants with generalized epilepsy:</p> <ul style="list-style-type: none"> • Generalized (Type II) seizure days per 28 days during the Evaluation Period. • Percent reduction in generalized (Type II) seizure days per 28 days from Baseline of the previous study to the Evaluation Period. • Responder rate for generalized (Type II) seizure days over the Evaluation Period. A responder was defined as a study participant with a $\geq 50\%$ reduction in seizure days from the Baseline Period of the previous study. • Percentage of study participants continuously seizure free for all seizure Types (I+II+III) for at least 6 months and at least 12 months during the Evaluation Period. <p>The following were evaluated separately for study participants with focal-onset epilepsy and study participants with generalized epilepsy:</p> <ul style="list-style-type: none"> • Change in QOLIE-31-P scores from Baseline of the previous study to each assessment for the first 2 years and to the last Evaluation Period assessment during the first 2 years. • EQ-5D Questionnaire response for each assessment for the first 2 years for the Evaluation Period and for the last assessment during the first 2 years of the Evaluation Period. 		

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	
No other efficacy variables were defined for study participants with ULD or coming from N01315.		
<p>Statistical methods: Descriptive statistics, such as the mean, standard deviation, median, minimum value, and maximum value for quantitative variables, and counts and percentages for categorical variables, are provided. In addition, for efficacy variables, the 25th percentile and 75th percentile are provided. No statistical hypothesis testing was performed in this study; all summaries are descriptive.</p> <p>Overall participant disposition was summarized for all enrolled participants (ie, all participants who signed informed consent), the Safety Analysis Set, and by subgroup of geographic region and indication for the Safety Analysis Set. A Modified Safety Analysis Set was also defined to consist of all study participants who took at least 1 dose of study drug including study participants entering the study from N01315.</p> <p>Demographic variables collected at the time of entry into the core study were summarized for the Safety Analysis Set. This summary was presented overall and by subgroups for geographic region and indication.</p> <p>The number and percentage of participants exposed to BRV were summarized overall and by the modal dose category. The number and percentage of participants in each Exposure Duration Cohort (≥ 3, ≥ 6, ≥ 12 months, and so forth) were summarized. The number and percentage of participants within each modal dose category were summarized for each Exposure Duration Cohort. Percentages were relative to the total number of participants in each Exposure Duration Cohort.</p> <p>Summaries of safety were provided for all participants in the Safety Analysis Set and also by subgroup for subgroups of geographic region and indication.</p> <p>For the analyses of maintenance of efficacy, cohorts were defined by 3-month time intervals, which were based on a 30-day month (eg, Months 1 to 3 corresponds to Days 1 to 90) and were defined relative to the first dose of BRV. A participant was included in summaries by efficacy time intervals if the participant was receiving BRV for at least the full duration of the 3-month interval based on their duration of exposure to BRV.</p> <p>Twenty-eight day adjusted seizure frequency for seizure types I, IA, IB, and IC, and for all seizure types (I+II+III) were calculated overall, within each 3-month time interval, and over each exposure duration cohort interval by dividing the total number of seizures for each seizure type by the number of days for which the diary was completed overall, within each 3-month interval, and within each exposure duration cohort interval, and multiplying the resulting value by 28.</p> <p>Percent reduction from Baseline for POS frequency was summarized with quantitative</p>		

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	

descriptive statistics for the On Treatment Period and by 3-month time intervals over the On Treatment Period. The summary over the On Treatment Period included all participants in the POS Efficacy Analysis Set. Similar summaries were provided for the full cohort interval and by 3-month time intervals for each exposure duration cohort. Percent reduction from Baseline for POS frequency was summarized in the same manner by geographic region.

Responders over the On Treatment Period were defined as participants with a $\geq 50\%$ reduction in 28-day adjusted POS frequency from Baseline to the On Treatment Period. A similar calculation applied to each 3-month time interval over the On Treatment Period and for the cohort interval for each exposure duration cohort.

The numbers and percentages of participants who were seizure free for all seizure types for any continuous 6-month interval, 12-month interval, 18-month interval, and so forth were summarized overall for the period of time that participants were being treated with BRV and by exposure duration cohort. The overall summary presented the number and percentage of participants who reported no seizures for the specified duration of seizure freedom and the seizure diary was completed for at least 90% of days within the seizure-free interval. Participants whose duration of BRV treatment was less than the specified duration of seizure freedom were considered failures for seizure freedom. Summaries by exposure duration cohort presented the number and percentage of participants who reported no seizures for the specified duration of seizure freedom at any time during the cohort interval (eg, through the end of Month 6 for the 6-month cohort) and the seizure diary was completed for at least 90% of days within the seizure-free interval. Percentages were relative to the number of participants within each exposure duration cohort.

Summary and conclusions:

Participant disposition: In N01125, a total of 853 participants were originally enrolled in the study, with an additional 6 participants enrolling from N01315 for a total of 859 participants; 859 participants were included in the Modified Safety Analysis Set, 853 participants were included in the Safety Analysis Set, 728 participants were included in the POS Efficacy Analysis Set, 30 participants were included in the PGS Efficacy Analysis Set, and 94 participants were included in the ULD Efficacy Analysis Set (Table 1.4). The most common reason for discontinuation was lack of efficacy (354 participants [41.5%]), followed by AEs (100 participants [11.7%]), and participant choice (98 participants [11.5%]).

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	

Safety results: The safety results are summarized as follows:

- All participants in the Safety Analysis Set (853 participants) received at least 1 dose of BRV for a total of 3477.5 participant-years of exposure. The most common modal doses of BRV were 150mg/day (415 participants [48.7%]) and 100mg/day (262 participants [30.7%]). Nine participants received a total daily dose of BRV >200mg/day during the Treatment Period, and all were considered important protocol deviations of incorrect treatment or dose; total daily doses ranged from 225mg to 300mg and all but one were for 1 day only. Two hundred seventy-four participants (32.1%) had at least 84 months of exposure to BRV.
- Overall, A total of 720 participants (84.4% [7407 events]) overall and 610 participants (83.7% [5964 events]) with POS reported at least 1 TEAE; of these, 199 participants (27.3% [410 events]) with POS reported a treatment-emergent SAE. Treatment-emergent AEs were most commonly reported in the system organ classes (SOCs) of Nervous system disorders (368 participants [43.1%]), Infections and infestations (286 participants [33.5%]), Gastrointestinal disorders (162 participants [19.0%]), and Psychiatric disorders (130 participants [15.2%]). The most common TEAEs (by PT) overall were headache (188 participants [22.0%]), nasopharyngitis (157 participants [18.4%]), and convulsion (137 participants [16.1%]).
 - A total of 157 participants (67.7%) and 422 participants (68.0%) who received placebo and BRV, respectively, in the previous study reported at least 1 TEAE in N01125. The incidence of TEAEs was similar (ie, ≤5% difference) between participants who received placebo and BRV in the previous study.
 - Overall, within TEAEs reported in ≥5% of participants, the incidence of TEAEs was higher in months 1 to 3 (473 participants [55.5%]) vs months 4 to 6 (282 participants [36.4%]), as well as subsequent months (range: 0 to 32.5%).
- The majority of TEAEs reported had a maximum intensity of mild or moderate; overall 171 participants (20.0%) and 333 participants (39.0%) reported TEAEs with a maximum intensity of mild or moderate, respectively, by the Investigator (Table 12.4.1). A total of 216 participants (25.3%) reported 478 TEAEs with a maximum intensity of severe (Table 12.1). Severe TEAEs reported by ≥1.0% of participants were headache (18 participants [2.1%]), convulsion (16 participants [1.9%]), and status epilepticus (10 participants [1.2%]).
- Treatment emergent AEs considered drug-related by the Investigator reported by ≥5% of participants included dizziness (60 participants [7.0%]), fatigue (53 participants [6.2%]), somnolence (52 participants [6.1%]), and convulsion (50 participants [5.9%]). All other

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	
<p>TEAEs assessed as drug-related by the Investigator were reported by <5% of participants.</p> <ul style="list-style-type: none"> • Nineteen deaths were reported in N01125; all deaths were reported in participants with POS or ULD. Two of the TEAEs resulting in death (death and aggression) were considered drug-related by the Investigator. • A total of 248 participants (29.1%) overall reported at least 1 treatment-emergent SAE. The most common treatment-emergent SAEs were in the SOC of Nervous system disorders (90 participants [10.6%]). The most common treatment-emergent SAE (by PT) was convulsion, reported by 36 participants (4.2%), followed by epilepsy (11 participants [1.3%]), and head injury and status epilepticus (10 participants [1.2%], each). • A total of 95 participants (11.1%) overall reported TEAEs leading to discontinuation of study drug. The most common TEAEs (by PT) leading to discontinuation of study drug were convulsion and pregnancy (9 participants [1.1%]); irritability and depression (5 participants [0.6%], each) and fatigue and suicidal ideation (4 participants [0.5%], each). • No clinically relevant findings were observed for any mean changes from Baseline in hematology, blood chemistry, urinalysis parameters, vital signs, body weight, or ECGs. • For participants in the Safety Analysis Set with ULD, the incidences of TEAEs overall, drug-related TEAEs, and the incidence of permanent discontinuation of study drug due to TEAE were comparable with the overall population; the incidence of severe TEAEs and treatment-emergent SAEs was higher compared with the overall population; there were 8 deaths (8.5%) reported for participants with ULD. • In participants with ULD, the most common TEAEs (by PT) were headache, urinary tract infection, somnolence, and diarrhea (24 participants [25.5%], 16 participants [17.0%], 16 participants [17.0%], and 15 participants [16.0%], respectively). • No meaningful interpretation could be drawn from the PGS Safety Populations due to the low number of participants. Nonetheless, there were no safety concerns in these participants. 		

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	

Efficacy results: Overall, at individualized doses up to a maximum of 200mg/day, administration of BRV resulted in the following:

- Participants on treatment reported a median POS frequency of 4.9 seizures per 28-day period, compared with Baseline median POS frequency of 8.4 seizures. Median POS frequency values decreased by exposure duration cohort from Baseline to the 84-month cohort.
- Participants on treatment reported a median (Q1, Q3) percent reduction in POS frequency from Baseline of 43.1% (9.9, 71.5) per 28-day period. Participants who remained in the study and on BRV treatment reported increasing median percent reductions from Baseline at each efficacy time interval assessed through 24 months (range: 43.8% to 59.0%) and remained stable through 132 months (range: 60.3% to 71.3%).
- Of the participants with POS on BRV treatment, 43.5% were 50% responders. For the participants with POS who remained in the study and on BRV treatment, the percentage of 50% responders increased consistently at each efficacy time interval assessed through 24 months and remained stable at approximately 60.0% through 84 months.
- Of the participants with POS on BRV treatment, 22.6% were seizure free for any continuous 6-month period of treatment.
- As anticipated in an LTFU of approximately 14 years, with increasing exposure duration, participants experienced an increase in continuous seizure freedom over time. However, with increasing exposure duration and within each exposure duration cohort, continuous seizure freedom for participants decreased over time.
- Overall, QOLIE-31-P and EQ-5D scores remained stable or were improving as early as 2 months and then remained stable through the Year 2 assessment (ie, 24 months).
- Overall, PGS participants on treatment reported a median (Q1, Q3) of 4.9 (0.6, 14.5) seizure days per 28-day period, a median percent reduction from Baseline in number of seizure days per 28-day period of 43.2%, and a 50% responder rate on treatment of 43.3%.
 - For PGS participants who remained in the study and on BRV treatment, the percentages of 50% responders increased through 36 months. Overall, 29.6% of the participants with PGS on BRV treatment after 6 months reported no seizures for any continuous 6-month period of treatment.

Name of company: UCB Pharma SA	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Not applicable	Volume: Not applicable	
Name of active ingredient: Brivaracetam	Page: Not applicable	
<p>Conclusions: N01125 gave study participants who participated in the previous studies, N01114, N01252, N01254, N01315 and N01187 or N01236, the opportunity to continue BRV treatment. The primary objective of N01125 was to evaluate the long-term safety and tolerability of BRV at individualized doses with a maximum dose of 200mg/day in study participants with epilepsy.</p> <ul style="list-style-type: none"> • Participants in N01125 received BRV for a total of 3477.5 participant-years of exposure. The most common modal doses were 150mg/day or 100mg/day. • The safety profile of BRV demonstrated in N01125 is consistent with that observed in other BRV studies. Overall, BRV was well tolerated at individualized doses with a maximum of 200mg/day in participants 16 years of age or older with epilepsy and no new observations related to safety were made. • In general, participants who remained in the study and on BRV treatment reported improvements in POS frequency and increasing percent reductions in POS frequency by exposure duration cohort from Baseline for each efficacy time interval assessed through at least the 84-month cohort. Within increasing exposure duration, participants experienced an increase in continuous seizure freedom over time. 		
Report date: 17 Oct 2019		