Poster P200

Brivaracetam Adjunctive Therapy in Paediatric and Adult Patients With Focal-Onset Seizures in Mid-European Countries: 12-Month, Real-World Outcomes from the BRIVA-REG Study

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Overview

QUESTION

What is the effectiveness of adjunctive brivaracetam (BRV) in a mixed population of paediatric and adult patients with focal-onset seizures (FOS) in the clinical standard-of-care setting?

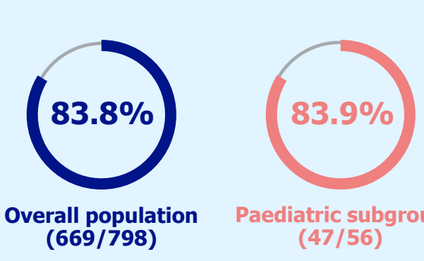
INVESTIGATION

BRIVA-REG (EP0099), a prospective, non-interventional, post-marketing study evaluating adjunctive BRV treatment in patients aged ≥4 years with FOS with or without focal to bilateral tonic-clonic seizures in the clinical practice setting. Patients were enrolled in 6 mid-European countries. Overall Safety Set: N=798; paediatric subgroup (<18 years): n=56.

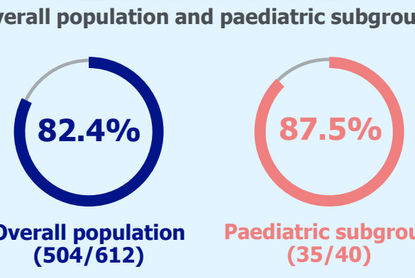
RESULTS (SAFETY SET)

Effectiveness

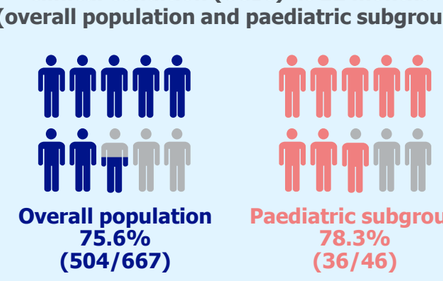
BRV retention rate at 12 months (overall population and paediatric subgroup)



≥50% responder rate in FOS frequency at 12 months versus baseline (overall population and paediatric subgroup)



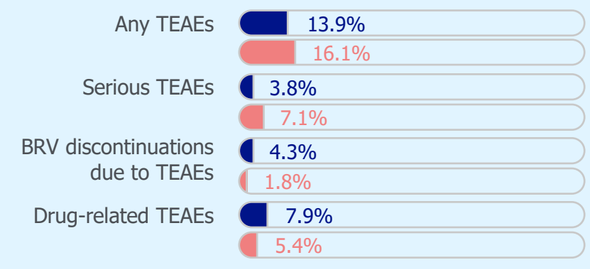
Patients showing any improvement[a] in clinical condition (CGIC) at 12 months (overall population and paediatric subgroup)



[a]Minimally, much, or very much improved.

Tolerability

- Incidence of TEAEs in the overall population (N=798)
- Incidence of TEAEs in the paediatric subgroup (n=56)



CGIC, Clinical Global Impression of Change; TEAE, treatment-emergent adverse event.

CONCLUSIONS

BRV retention and ≥50% responder rates at 12 months suggest adjunctive BRV was effective in paediatric patients (<18 years) with FOS in routine clinical practice in mid-European countries; results were similar in the overall population of patients with FOS. In the paediatric subgroup and in the overall population, respectively, >78% and >75% of physicians reported improved condition in their patients at 12 months versus baseline (CGIC). BRV was well tolerated both in paediatric patients and in the overall population.

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Background

- In the European Union, brivaracetam (BRV) is indicated as adjunctive therapy in the treatment of focal-onset (partial-onset) seizures, or FOS, with or without focal to bilateral tonic-clonic (secondary generalised) seizures in adults, adolescents, and children from 2 years of age with epilepsy.[1]
- Real-world evidence for adult and paediatric patients treated with BRV in the routine clinical setting is scarce in Eastern European countries.
- The prospective, non-interventional BRIVAracetam REGistry (BRIVA-REG; EP0099) study aimed to close this knowledge gap, and offers valuable insights into adjunctive BRV use and effectiveness in real-world settings.

Objective

- To evaluate the effectiveness of adjunctive BRV in a mixed population of paediatric (<18 years) and adult patients with FOS in the clinical standard-of-care setting, with a focus on paediatric data.

Methods

STUDY DESIGN

- BRIVA-REG (EP0099) was a prospective, non-interventional, post-marketing study with an observational period of approximately 12 months.
- BRIVA-REG enrolled paediatric and adult patients aged ≥4 years with FOS with or without focal to bilateral tonic-clonic seizures in mid-European countries: Bulgaria, Czech Republic, Greece, Hungary, Poland, and Romania.
- Eligible patients had not received BRV treatment before study entry and were receiving ≥1 antiseizure medication at BRV initiation.
- BRV was prescribed according to routine clinical practice and in accordance with the Summary of Product Characteristics approved in Europe at the time of enrolment.
- The decision by the treating physician to prescribe BRV was made independently from participation in the study.
- The first patient was enrolled in December 2021. The last patient's last visit occurred in July 2024.
- Baseline seizure frequency was based on the 3 months before visit 1 (baseline).
- Baseline Patient Weighted Quality of Life in Epilepsy Inventory-Form 31 (QOLIE-31-P) and Pediatric Quality of Life Inventory (PedsQL) total scores were based on questionnaires completed at visit 1.
- The Helpilepsy™ application, a digital solution for real-time disease monitoring for patients and physicians, was used for patient questionnaires; paper questionnaires were not available.

OUTCOMES AND MEASUREMENTS

- This poster presents data for the overall Safety Set (SS), which includes patients with valid data consent who received ≥1 BRV dose, and for the paediatric subgroup (as part of the overall SS).
- Outcomes included:
  - BRV retention rate at 12 months after treatment initiation, in the overall population and in the paediatric subgroup
  - ≥50% responder rate (≥50% reduction from baseline in FOS frequency) at 12 months after BRV treatment initiation, in the overall population and in the paediatric subgroup
  - Clinical Global Impression of Change (CGIC) ratings at 12 months (the patient's condition over the past 4 weeks compared with baseline) in the overall population and in the paediatric subgroup
  - QOLIE-31-P total scores at baseline, 6 months, and 12 months, and clinically meaningful change from baseline to 6 and 12 months, in the adult subgroup
  - PedsQL total scores at baseline and 6 months, in the subgroup of patients aged ≥8 to <18 years
  - Treatment-emergent adverse events (TEAEs) in the overall population and in the paediatric subgroup.
- Some paediatric data were analysed post hoc: patient demographics and baseline characteristics, BRV retention rate at 12 months, ≥50% responder rate in FOS frequency at 12 months, CGIC ratings at 12 months, and TEAEs.

Results

DISPOSITION, DEMOGRAPHICS, AND BRV DOSING

- The overall SS included 798 patients, of whom 56 (7.0%) were paediatric patients at baseline (≥4 to <18 years).

Patient demographics and baseline characteristics (SS)

	OVERALL POPULATION (N=798)	PAEDIATRIC SUBGROUP (n=56)
Age at visit 1, median (Q1, Q3), years	40.0 (27, 52)	13.0 (8, 16)
Female, n (%)	429 (53.8)	24 (42.9)
Helpilepsy™ user, n (%)	288 (36.1)	18 (32.1)
Time since first diagnosis of epilepsy, median (Q1, Q3), years	14.41 (6.11, 28.25)	7.23 (3.20, 9.86)
>10 years, n (%)	500 (62.7)	11 (19.6)
Number of prior ASMs[a], median (Q1, Q3)	2.0 (1.0, 3.0)[b]	2.0 (1.0, 3.0)[c]
Number of lifetime ASMs[d], median (Q1, Q3)	3.0 (2.0, 5.0)[e]	3.0 (2.0, 4.5)
Number of concomitant ASMs at BRV initiation[f], median (Q1, Q3)	2.0 (1.0, 2.0)[g]	2.0 (1.0, 3.0)[h]

[a]Prior ASMs are defined as ASMs discontinued before the date of first BRV administration; [b]n=633; [c]n=36; [d]Lifetime ASMs are defined as the sum of the prior ASMs and concomitant ASMs at BRV initiation, excluding benzodiazepines or other rescue medications used short term per physician discretion; [e]n=796; [f]Concomitant ASMs at BRV initiation are ASMs taken on the same day or ongoing at the day of first BRV administration; [g]n=777; [h]n=53. ASM, antiseizure medication; Q1, 25th percentile; Q3, 75th percentile; SS, Safety Set.

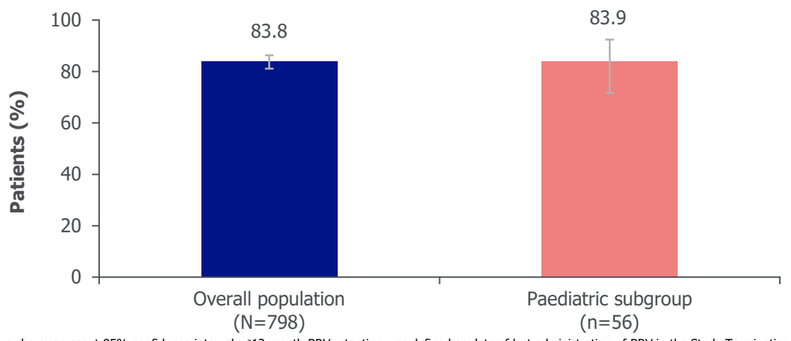
BRV total daily dose (SS)

n MEDIAN (Q1, Q3)	PAEDIATRIC SUBGROUP: WEIGHING ≥10 to <20 kg (mg/kg/DAY)	PAEDIATRIC SUBGROUP: WEIGHING ≥20 to <50 kg (mg/kg/DAY)	PAEDIATRIC SUBGROUP: WEIGHING ≥50 kg (mg/DAY)	ADULT SUBGROUP (mg/DAY)
Visit 1	n=5 2.00 (1.92, 2.67)	n=26 2.03 (1.61, 2.63)	n=25 100 (100, 200)	n=742 100 (100, 200)
12 months	n=4 2.71 (2.33, 3.38)	n=22 2.62 (2.00, 3.26)	n=22 175 (100, 200)	n=641 200 (100, 200)

Q1, 25th percentile; Q3, 75th percentile; SS, Safety Set.

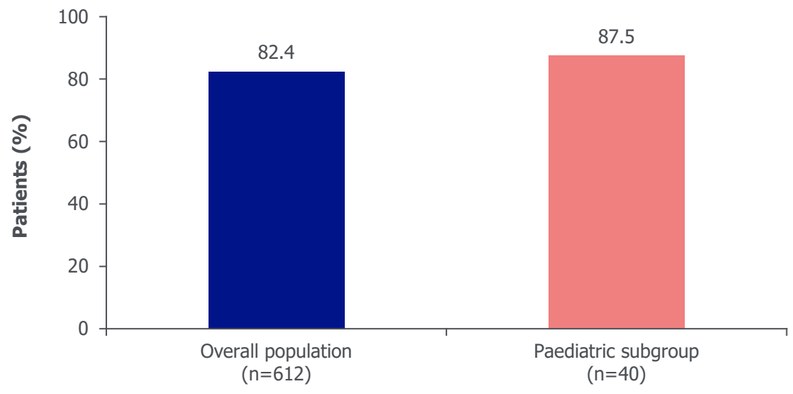
EFFECTIVENESS

BRV retention rate at 12 months[a] (SS)



Error bars represent 95% confidence intervals. [a]12-month BRV retention was defined as date of last administration of BRV in the Study Termination electronic case report form or Study Medication Discontinuation electronic case report form – date of first BRV administration +1 ≥330 days.
SS, Safety Set.

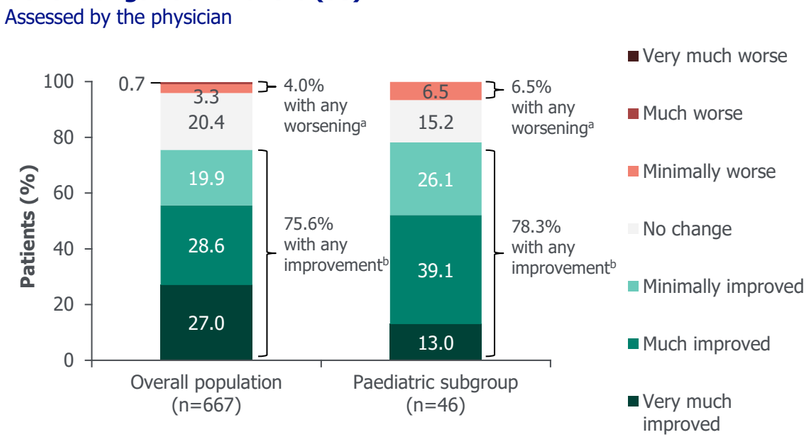
≥50% responder rate in FOS frequency at 12 months versus baseline (SS)



FOS, focal-onset seizure; SS, Safety Set.

CGIC ratings at 12 months (SS)

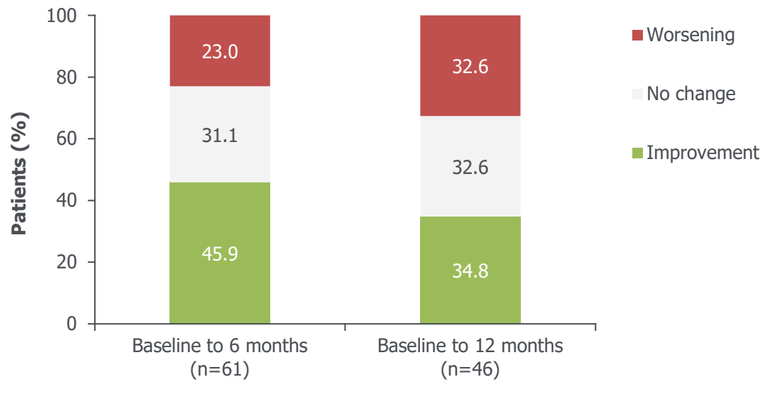
Assessed by the physician



The CGIC is a 7-point categorical rating scale in which the physician is asked to check the number that best describes the patient's condition over the past 4 weeks compared with baseline. Only the data observed before BRV discontinuation (on BRV) were analysed. [a]Any worsening is the sum of minimally worse and much worse (no patients reported very much worse); [b]Any improvement is the sum of minimally improved, much improved, and very much improved.
CGIC, Clinical Global Impression of Change; SS, Safety Set.

Clinically meaningful change in QOLIE-31-P total score from baseline to 6 and 12 months in the adult subgroup (SS)

Assessed by the patient



QOLIE-31-P scores range from 0 to 100, with a higher score reflecting better functioning. Only the data observed before BRV discontinuation (on BRV) were analysed. Clinically meaningful categories are defined according to Borghs et al.[2]
QOLIE-31-P, Patient Weighted Quality of Life in Epilepsy Inventory-Form 31; SS, Safety Set.

- Median QOLIE-31-P total score was 60.11, 65.36, and 60.88 at baseline (n=131), 6 months (n=82), and 12 months (n=59), respectively.
- Median change from baseline to 6 months was 3.37 (n=61); median change from baseline to 12 months was 0.99 (n=46).

Change in PedsQL total score from baseline to 6 months[a] in the subgroup of patients aged ≥8 to <18 years (SS)

Assessed by the patient

	SUBGROUP OF PATIENTS AGED ≥8 to <18 YEARS
Observed score at baseline, median (Q1, Q3), n	66.33 (46.48, 81.80), n=8
Observed score at 6 months, median (Q1, Q3), n	80.47 (50.00, 88.44), n=4
Change from baseline to 6 months, median (min, max), n	5.47 (−0.9, 31.3), n=3

PedsQL scores range from 0 to 100, with a higher score reflecting better functioning. Only the data observed before BRV discontinuation (on BRV) were analysed. [a]Summary statistics are not available at 12 months (n=2).
Max, maximum; min, minimum; PedsQL, Pediatric Quality of Life Inventory; Q1, 25th percentile; Q3, 75th percentile; SS, Safety Set.

SAFETY AND TOLERABILITY

Incidence of TEAEs (SS)

CATEGORY, n (%) [# EVENTS]	OVERALL POPULATION (N=798)	PAEDIATRIC SUBGROUP (n=56)
Any TEAEs[a]	**111 (13.9) [189]**	**9 (16.1) [17]**
Serious TEAEs	30 (3.8) [51]	4 (7.1) [6]
BRV discontinuations due to TEAEs	34 (4.3) [50]	1 (1.8) [1]
Drug-related TEAEs[b]	63 (7.9) [96]	3 (5.4) [3]
Behavioural TEAEs[c]	8 (1.0) [10]	2 (3.6) [3]
All deaths (AEs leading to death)	4 (0.5) [4]	0

[a]A TEAE was defined as an AE occurring on or after the date of first BRV administration and up to 30 days after BRV discontinuation. [b]Drug-related TEAEs were defined per investigator's assessment. Missing relationship was treated as missing and was not counted; [c]Classification of a TEAE as behavioural was based on a list of selected preferred terms.
AE, adverse event; SS, Safety Set; TEAE, treatment-emergent adverse event.

Limitations

- The use of Helpilepsy™ as the only option to collect patient-reported outcome data was a possible limitation.
- Caution should be applied when interpreting patient-reported data due to low sample sizes.

Conclusions

- BRIVA-REG provides prospective, real-world evidence for the effectiveness of adjunctive BRV in patients with FOS, including a subgroup of paediatric patients (<18 years).
- BRV retention and ≥50% responder rates at 12 months suggest adjunctive BRV was effective in paediatric patients with FOS in routine clinical practice in mid-European countries (SS).
  - Results were similar in the overall population.
- In the paediatric subgroup and in the overall population, respectively, >78% and >75% of physicians reported improved condition in their patients at 12 months versus baseline (CGIC).
- BRV was well tolerated both in paediatric patients and in the overall population.

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1. Briviact® (brivaracetam) European Union Summary of Product Characteristics. UCB Pharma SA. 2024. https://www.ema.europa.eu/en/documents/product-information/briviact-epar-product-information_en.pdf Accessed 10 July 2025.
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