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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Assessed by the patient

^aSummary statistics are not available at 12 months (n=2)

Incidence of TEAEs (SS)

CATEGORY, n (%) [# EVENTS]

BRV discontinuations due to **TEAEs**

All deaths (AEs leading to death)

Any TEAEsa

Serious TEAEs

SAFETY AND TOLERABILITY

3. Epilepsy Center, Bethesda Children's

5. Medical University of Sofia, Sofia,

6. Bucharest University Emergency Hospital, Bucharest, Romania

7. Charles University and Motol **University Hospital, Prague, Czech** Republic*; Medicon a.s., Prague,

8. Brno Epilepsy Center, First
Department of Neurology, St. Anne's
University Hospital and Faculty of Medicine, Masaryk University, Brno

Poster PO02-343

SUBGROUP OF PATIENTS

AGED ≥8 to <18 YEARS

66.33 (46.48, 81.80), n=8

80.47 (50.00, 88.44), n=4

5.47 (-0.9, 31.3), n=3

PAEDIATRIC

SUBGROUP

(n=56)

9 (16.1) [17]

4 (7.1) [6]

1 (1.8) [1]

3 (5.4) [3]

2 (3.6) [3]

9. UCB, Oakville, Ontario, Canada 10.UCB, Monheim am Rhein, Germany 11. UCB, Prague, Czech Republic

*Full member of ERN EpiCARE

Change in PedsQL total score from baseline to 6 months^a, in the

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.

OVERALL

POPULATION

(N=798)

111 (13.9) [189]

30 (3.8) [51]

34 (4.3) [50]

63 (7.9) [96]

8 (1.0) [10]

4 (0.5) [4]

subgroup of patients aged ≥8 to <18 years (SS)

Change from baseline to 6 months, median (min, max), n

Max, maximum; min, minimum; PedsQL, Pediatric Quality of Life Inventory; Q1, 25th percentile; Q3, 75th percentile; SS, Safety Set

Observed score at baseline, median (Q1, Q3), n

Observed score at 6 months, median (Q1, Q3), n

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
- 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
- $\ge 50\%$ responder rate ($\ge 50\%$ 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.

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.

(?) QUESTION

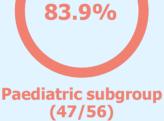
RESULTS (SAFETY SET)

in the clinical standard-of-care setting?

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



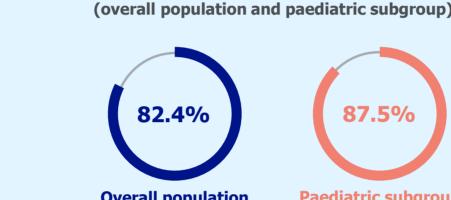
E CONCLUSIONS



BRV was well tolerated both in paediatric patients and in the overall population.

What is the effectiveness of adjunctive brivaracetam (BRV) in a mixed

population of paediatric and adult patients with focal-onset seizures (FOS)



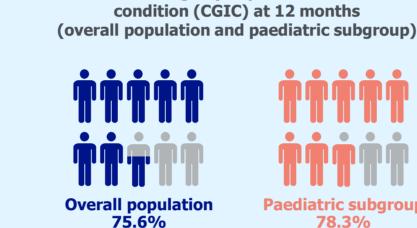
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Effectiveness

≥50% responder rate in FOS frequency

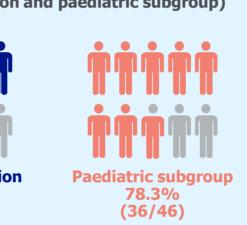
at 12 months versus baseline



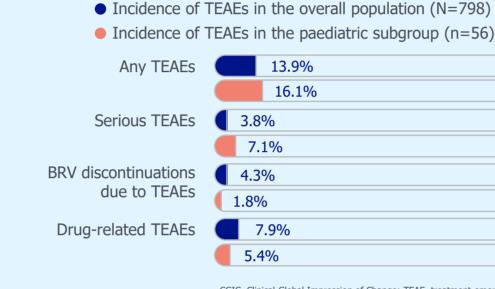
BRV retention and ≥50% responder rates at 12 months suggest adjunctive BRV was effective in paediatric patients (<18 years) with FOS in routine clinical practice in mid-European countries; results were similar in the

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).

(504/667)



Patients showing any improvement^a in clinical



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

Tolerability

AE, adverse event; SS, Safety Set; TEAE, treatment-emergent adverse event.

Drug-related TEAEsb

Behavioural TEAEs^c

Limitations • The use of Helpilepsy[™] as the only option to collect patient-reported outcome data was a possible limitation.

^aA TEAE was defined as an AE occurring on or after the date of first BRV administration and up to 30 days after BRV discontinuation. ^bDrug-related TEAEs were defined

Caution should be applied when interpreting patient-reported data due to low

Results

DISPOSITION, DEMOGRAPHICS, AND BRV DOSING

• The overall Safety Set 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 ASMsa, 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

^aPrior ASMs are defined as ASMs discontinued before the date of first BRV administration; ^bn=633; ^cn=36; ^dLifetime 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; en=796; fConcomitant 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)

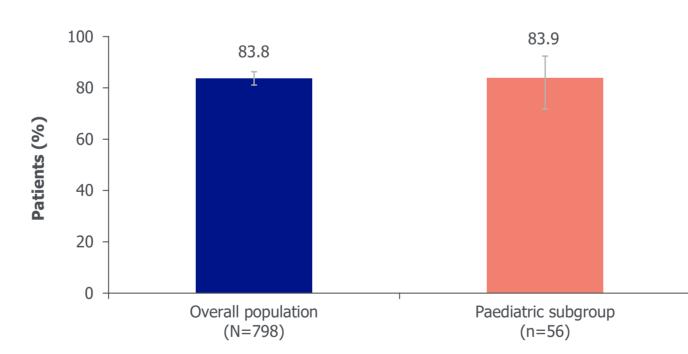
	PAEDIATRIC SUBGROUP			
n	WEIGHING	WEIGHING	WEIGHING	ADULT
MEDIAN	≥10 to <20 kg	≥20 to <50 kg	≥50 kg	SUBGROUP
(Q1, Q3)	(mg/kg/DAY)	(mg/kg/DAY)	(mg/DAY)	(mg/DAY)
Visit 1	n=5	n=26	n=25	n=742
	2.00	2.03	100	100
	(1.92, 2.67)	(1.61, 2.63)	(100, 200)	(100, 200)
12 months	n=4	n=22	n=22	n=641
	2.71	2.62	175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

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

EFFECTIVENESS

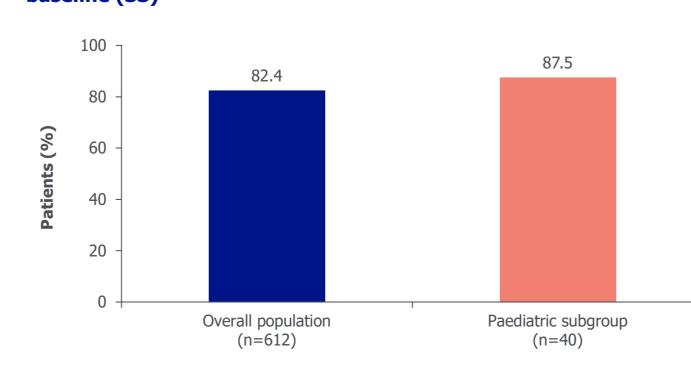
FOS, focal-onset seizure; SS, Safety Set.

BRV retention rate at 12 months^a (SS)

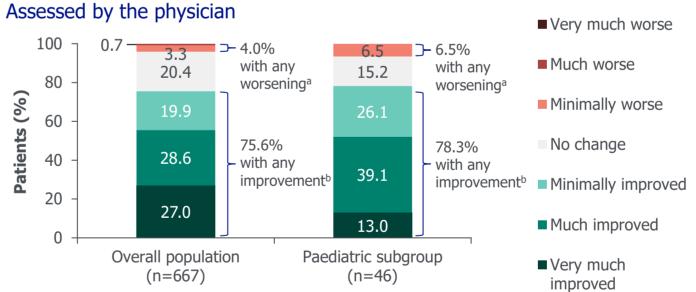


Error bars represent 95% confidence intervals. 312-month BRV retention was defined as date of last administration of BRV in the Study Termination electronic case report form or Study Medication Discontinuation electronic case report form – date of first BRV administration +1 ≥330 days. SS, Safety Set.

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

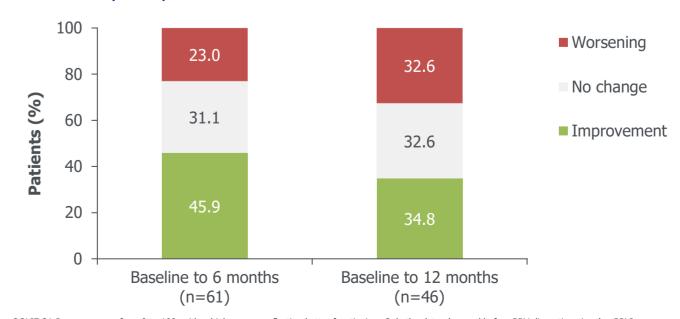


CGIC ratings at 12 months (SS)



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. Any worsening is the sum of minimally worse and much worse (no patients reported very much worse): bAny 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).

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.

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 8 May 2025. 2. Borghs S, et al. Epilepsy Behav 2012;23(3):230-234.

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