

# A 12-MONTH NONINTERVENTIONAL OBSERVATIONAL MULTINATIONAL STUDY TO EVALUATE EFFECTIVENESS, TOLERABILITY, AND QUALITY OF LIFE OF BRIVARACETAM ADJUNCTIVE THERAPY IN EARLIER TREATMENT LINES IN ADULT PATIENTS WITH HISTORY OF PARTIAL-ONSET SEIZURES IN DAILY CLINICAL PRACTICE (BRITOPA)

**First published:** 28/05/2021

**Last updated:** 09/01/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS41206

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### Study ID

50035


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## **DARWIN EU® study**

No

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### **Study countries**

 Canada

 France

 Germany

 Italy

 Spain

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### **Study description**

EP0103 is a post-marketing, multinational, observational, prospective non-interventional study (NIS) to evaluate effectiveness, tolerability, and quality of life of adjunctive Brivaracetam (BRV) therapy in earlier treatment line combinations in adult patients with history of partial-onset seizures (POS). In addition, this study may allow the exploration of predictions of response in patients in earlier treatment line combinations. Brivaracetam will be prescribed according to standard clinical practice.

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### **Study status**

Finalised

## **Contact details**

### **Study institution contact**

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available. [clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

## Study contact

[clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

### Primary lead investigator

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.

## Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 09/07/2020

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### Study start date

Actual: 11/12/2020

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### Data analysis start date

Planned: 28/02/2024

Actual: 20/02/2024

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### Date of final study report

Planned: 30/06/2024

Actual: 10/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

UCB Biopharma SRL

## Study protocol

[ep0103-protocol-amendment-2-public.pdf](#) (2.33 MB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Tolerability, health-related quality of life and treatment satisfaction

**Main study objective:**

The primary objective of the study is to evaluate the effectiveness of BRV in earlier treatment line combinations in patients with POS with or without secondary generalization for approximately 12 months of treatment.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

BRIVARACETAM

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**Medical condition to be studied**

Partial seizures

## Population studied

## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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## **Estimated number of subjects**

400

# Study design details

## **Outcomes**

Seizure freedom for at least 6 consecutive months over a 12-month observation period. -BRV retention at 3, 6, 9 & 12 months -Seizure freedom at 3, 6, 9, & 12 months -POS frequency at Baseline, 3, 6, 9, & 12 months -Change (absolute & percent) in POS frequency from Baseline to 3, 6, 9, & 12 months -Response based on percent change in POS frequency at 3, 6, 9, & 12 months - Discontinuation of BRV due to lack of effectiveness -Time to discontinuation of BRV treatment

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## **Data analysis plan**

Variables will be summarized using descriptive statistics. For continuous variables, summary statistics (number of available observations, mean, standard deviation, minimum, median, maximum, and 25% and 75% quartiles where relevant) will be tabulated. Categorical variables will be summarized by the frequency and percentage of patients in each category. The primary endpoint is the proportion of patients achieving six consecutive months of seizure freedom over the duration of the 12-month study and will be presented

with a 2-sided 95% confidence interval (CI). Secondary endpoints include percentage change in POS frequency (change from baseline) and proportion of patients experiencing retention of BRV. Patient reported outcomes (PROs) will be presented using frequency distributions or change from baseline of total scores or domain scores (as applicable). Summary of safety endpoints include focus on incidence rates of AEs and BRV dosing.

## Documents

### Study report

[EP0103-study-report-public.pdf](#) (2.29 MB)

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No