



UCB  
News

## **New indication for BRIVIACT<sup>®</sup> (brivaracetam): UCB's newest antiepileptic drug approved by FDA as monotherapy treatment of partial-onset seizures in adults**

- **BRIVIACT<sup>®</sup> CV provides a new monotherapy treatment option for epilepsy patients 16 years of age and older with partial-onset (focal) seizures, which can be initiated at a therapeutic dose at day one.**
- **Approval applies a newly established regulatory pathway which allows monotherapy treatment options to reach epilepsy patients sooner.**
- **New indication comes just 18 months after launch of BRIVIACT<sup>®</sup> in the U.S.**

**Atlanta, Georgia (U.S.) & Brussels (Belgium), 15 September, 2017:** UCB announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for BRIVIACT<sup>®</sup> (brivaracetam) CV as monotherapy for partial-onset (focal) seizures (POS) in patients 16 years and older with epilepsy.<sup>1</sup>

This is a new indication for BRIVIACT, which is already approved in the U.S. as adjunctive treatment for POS in patients in this age group. As a result, adults and adolescents aged 16 years and older with POS in the U.S. can now be initiated on BRIVIACT as monotherapy or adjunctive therapy.

BRIVIACT is the newest antiepileptic drug (AED) in the 'racetam' class of medicines and demonstrates a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to its anticonvulsant effects. Gradual dose escalation is not required when initiating treatment with BRIVIACT for monotherapy or adjunctive therapy, allowing clinicians to initiate treatment at a therapeutic dose from day one.<sup>1</sup>

The most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) are somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms.<sup>1</sup> Please see additional BRIVIACT Important Safety Information below.

*“This new monotherapy indication builds on an already strong and compelling clinical profile for BRIVIACT, providing doctors the flexibility to tailor their choice of AED to match individual patient needs and circumstances,” explained Dr. Pavel Klein, director of the Mid-Atlantic Epilepsy and Sleep Center. “In helping to progress their journey towards seizure freedom by providing a choice of treatment which can be initiated as monotherapy, at a therapeutic dose, from day one, BRIVIACT provides an additional treatment choice for neurologists and their patients.”*

UCB submitted a supplemental application for a BRIVIACT monotherapy indication taking into account a recent General Advice Letter, issued by the FDA,<sup>2</sup> which stated it is acceptable to extrapolate the efficacy and safety of drugs approved as adjunctive therapy for the treatment of POS to their use as monotherapy for the treatment of POS. As a result of the FDA’s approach to assessing extrapolated data, UCB was able to support its BRIVIACT monotherapy submission with a wealth of brivaracetam clinical trials data, which involved more than 2,400 adult patients with POS.<sup>1</sup>

*“We are delighted that, with this new monotherapy indication for BRIVIACT, we can support people with epilepsy to reach their treatment goals. Coming just 18 months after our launch in the U.S., this is evidence of our commitment to increasing the speed at which our therapies are approved and made available to as many patients as possible,” explained Jeff Wren, Executive Vice-President, Head of UCB’s Neurology Patient Value Unit. “Discovering, validating and improving access to new and innovative solutions to support people living with epilepsy has been, and will continue to be, a core UCB mission. With this BRIVIACT monotherapy indication, we build on our longstanding commitment to help people with seizure disorders at every point of their journey.”*

### **About Epilepsy<sup>3,4,5,6</sup>**

Epilepsy is a chronic neurological disorder of the brain. It is the fourth most common neurological condition worldwide and affects approximately 65 million people. In the U.S., more than 3 million people have epilepsy. Anyone can develop epilepsy; it occurs across all ages, races and genders, and is defined as one or more unprovoked seizures with a risk of further seizures. Around one third of patients with epilepsy currently live with uncontrolled seizures.

## About UCB in Epilepsy

UCB has a rich heritage in epilepsy with over 20 years of experience in the research and development of antiepileptic drugs. As a company with a long-term commitment to epilepsy research, our goal is to address unmet medical needs. Our scientists are proud to contribute to advances in the understanding of epilepsy and its treatment. We partner and create super-networks with world-leading scientists and clinicians in academic institutions, pharmaceutical companies and other organizations who share our goals. At UCB, we are inspired by patients, and driven by science in our commitment to support patients with epilepsy.

## About BRIVIACT<sup>1,7</sup>

BRIVIACT (brivaracetam) is a new molecular entity that was rationally designed and developed by UCB.

Brivaracetam displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect. However, the precise mechanism of action by which BRIVIACT exerts its anticonvulsant activity is not known.

In the U.S., BRIVIACT is approved as monotherapy and adjunctive therapy (a therapy used together with primary treatment) for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. BRIVIACT is available in three formulations (film-coated tablets, oral solution, and injection).

In the European Union, BRIVIACT is approved as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. The European Medicines Agency has different regulatory requirements from FDA for approval of monotherapy indications.

## Important Safety Information about BRIVIACT<sup>®</sup> in the U.S.<sup>1</sup>

### Warnings and Precautions

- **Suicidal Behavior and Ideation:** Antiepileptic drugs, including BRIVIACT, increase the risk of suicidal behavior and ideation. Monitor patients taking BRIVIACT for the emergence or

worsening of depression; unusual changes in mood or behavior; or suicidal thoughts, behavior, or self-harm. Advise patients, their caregivers, and/or families to be alert for these behavioral changes and report them immediately to a healthcare provider.

- **Neurological Adverse Reactions:** BRIVIACT causes somnolence, fatigue, dizziness, and disturbance in coordination. Somnolence and fatigue-related adverse reactions were reported in 25% of patients taking at least 50 mg per day of BRIVIACT compared to 14% of patients taking placebo. Dizziness and disturbance in gait and coordination were reported in 16% of patients taking at least 50 mg per day of BRIVIACT compared to 10% of patients taking placebo. The risk is greatest early in treatment but can occur at any time. Monitor patients for these signs and symptoms and advise them not to drive or operate machinery until they have gained sufficient experience on BRIVIACT.
- **Psychiatric Adverse Reactions:** BRIVIACT causes psychiatric adverse reactions, including non-psychotic and psychotic symptoms. These events were reported in approximately 13% of patients taking at least 50 mg per day of BRIVIACT compared to 8% of patients taking placebo. A total of 1.7% of adult patients taking BRIVIACT discontinued treatment due to psychiatric reactions compared to 1.3% of patients taking placebo. Advise patients to report these symptoms immediately to a healthcare provider.
- **Hypersensitivity:** BRIVIACT can cause hypersensitivity reactions. Bronchospasm and angioedema have been reported. Discontinue BRIVIACT if a patient develops a hypersensitivity reaction after treatment. BRIVIACT is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.
- **Withdrawal of Antiepileptic Drugs:** As with all antiepileptic drugs, BRIVIACT should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

### Dosing Considerations

- Dose adjustments are recommended for patients with all stages of hepatic impairment.
- When BRIVIACT is co-administered with rifampin, an increase in the BRIVIACT dose is recommended.



## Adverse Reactions

The most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) are somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms.

## BRIVIACT is a Schedule V controlled substance.

Please refer to full Prescribing Information at <http://www.briviact.com/briviact-PI.pdf>.

For more information on BRIVIACT, contact 844-599-CARE (2273).

BRIVIACT® is a registered trademark of the UCB Group of Companies.

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## About UCB

UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 7500 people in approximately 40 countries, the company generated revenue of € 4.2 billion in 2016. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB\_news

## Forward looking statements - UCB

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results

and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

## References:

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