Inspired by **patients.**
Driven by **science.**

BRIVIACT® now available in U.S. pharmacies for epilepsy patients living with partial-onset seizures

- BRIVIACT® (brivaracetam) CV recently approved by U.S. FDA as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy, and now available[1]
- With BRIVIACT® patients can start with a therapeutic dose on day one
- People with epilepsy are living with unmet needs, as approximately 30% remain uncontrolled on existing therapies and still experience seizures[2]
- UCB has a longstanding heritage in developing differentiated treatment solutions for people living with epilepsy; regulatory filings in countries worldwide are underway

Brussels, Belgium – 31 May, 7:30 AM CET – Today UCB announced that BRIVIACT® (brivaracetam) CV, approved as adjunctive therapy for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy, is now available in U.S. pharmacies across the country. BRIVIACT® is available in three formulations: film-coated tablets, oral solution and injection. Injection may be used when oral administration is temporarily not feasible. Injection (single-dose vials) will be available in pharmacies in June.

BRIVIACT® is a new molecular entity that was approved by the U.S. Food and Drug Administration (FDA) on February 18, 2016, providing an important new treatment option for those living with epilepsy. On May 12, 2016, the Drug Enforcement Administration (DEA) listed BRIVIACT® as a Schedule V controlled substance.

Gradual dose escalation is not required when initiating treatment with BRIVIACT®. The recommended starting dosage is 50 mg twice daily (100 mg per day). Based on individual patient tolerability and therapeutic response, the dosage may be adjusted down to 25 mg twice daily (50 mg per day) or up to 100 mg twice daily (200 mg per day).

"What It is important to note that with BRIVIACT® is that titration is not required to achieve a therapeutic dose. Patients can start their very first BRIVIACT® treatment with a therapeutic dose. This makes it a useful addition to the current antiepileptic medication armamentarium," said Dr. Pavel Klein, MD, Director, Mid-Atlantic Epilepsy and Sleep Center, Bethesda, Maryland.

BRIVIACT® is associated with important warnings and precautions including suicidal behavior and ideation, somnolence, fatigue, dizziness, disturbance in gait and coordination, psychiatric adverse reactions including non-psychotic and psychotic symptoms, and hypersensitivity reactions (bronchospasm and angioedema). BRIVIACT® is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients. 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.[1]

Patients with epilepsy are living with significant unmet needs. Approximately 30% of people with epilepsy [illegible] uncontrolled on existing therapies and still experience seizures, which can lead to devastating physical ar[illegible]

emotional consequences.[2,3] Epilepsy can develop in anyone at any age, and approximately one in 26 people will develop epilepsy in their lifetime.[4]

"At UCB, we are constantly inspired to improve patients' lives, which is why we are excited that BRIVIACT® is now available in U.S. pharmacies. This is an important addition to our existing epilepsy portfolio," said Jeff Wren, Head of Neurology and Executive Vice President at UCB. "We remain steadfast in our commitment to addressing unmet needs for people with epilepsy, and will continue our efforts to bring this important treatment to even more patients worldwide."

In January 2016, the European Commission granted the marketing authorization for BRIVIACT® as an adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent patients from 16 years of age with epilepsy. In the EU, BRIVIACT® is already available to patients in the UK, Germany, and Denmark. In Canada, brivaracetam is approved as the trade name BRIVLERA®. UCB has submitted additional regulatory applications for brivaracetam in other countries including Australia, Brazil, Russia, Switzerland and Turkey.

About BRIVIACT®

BRIVIACT® 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. BRIVIACT® is available in three formulations (film-coated tablets, oral solution, and injection).[1,5]

IMPORTANT SAFETY INFORMATION

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.

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.

About Epilepsy[4,6,7,8,9]

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide and more than 2 million people in the U.S. It is the fourth most common neurological disorder in the U.S. Although epilepsy may be linked to factors such as health conditions, race and age, it can develop in anyone at any age. Approximately one in 26 people will develop epilepsy in their lifetime.

There are many different types of epilepsy, but the main characteristic of the condition is recurrent seizures. Seizures are classified by the pattern of onset—partial seizures start in one part of the brain and generalized seizures are characterized by widespread involvement of the whole brain.

Epilepsy is considered to be a disease of the brain defined by any of the following conditions: (1) at least two unprovoked (or reflex) seizures occurring >24 hours apart; (2) one unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years; (3) diagnosis of an epilepsy syndrome.

About UCB in Epilepsy

UCB has a rich heritage in epilepsy with more than 20 years of experience in the research and development of anti-epileptic 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.

For further information

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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 in immunology and neurology. With more than 7500 people in approximately 40 countries, the company generated revenue of €3.9 billion in 2015. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements

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. Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. UCB is providing this information as of the date of this document 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.

USP-BRV0516-0135

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