UCB News

U.S. FDA approves UCB's new epilepsy treatment, BRIVIACT®, for patients with partial-onset seizures

- BRIVIACT® (brivaracetam), a new molecular entity, is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy[1]
- The approximately 30% of people with epilepsy whose seizures remain uncontrolled on currently available therapies can experience devastating physical and emotional consequences as a result[2,3]
- Phase 3 data showed BRIVIACT® significantly reduced the frequency of partial-onset seizures over placebo[1]
- The FDA approval of BRIVIACT® once again demonstrates UCB's commitment to and expertise in delivering promising new treatments to people living with epilepsy; regulatory filings in countries worldwide are underway

Brussels, Belgium – 19 February, 6 pm CET – Today UCB announced that the U.S. Food and Drug Administration (FDA) has approved BRIVIACT® (brivaracetam) as adjunctive therapy (a therapy used together with primary treatment) in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. The Drug Enforcement Administration is anticipated to classify BRIVIACT® according to the drug scheduling process within the next 90 days, after which time BRIVIACT® will become commercially available in the U.S.[1]

"The FDA's approval of BRIVIACT® is significant, because uncontrolled seizures can have serious, long-term effects, and approximately 30% of epilepsy patients remain uncontrolled on currently available treatments," said Dr. Pavel Klein, MD, Director, Mid-Atlantic Epilepsy and Sleep Center, Bethesda, Maryland.

"We are excited to introduce BRIVIACT® as a new therapeutic option that may make a difference in the lives of people with epilepsy in the U.S.," said Jeff Wren, Head of Neurology and Executive Vice President at UCB. "This approval is the culmination of more than eight years of clinical trials involving more than 2,400 adult patients with partial-onset seizures. The development of BRIVIACT® builds upon our longstanding heritage in developing meaningful treatment solutions for people living with epilepsy."

The approved indication is based on data from three pivotal Phase 3 studies (Studies N01252, N01253 and N01358), in which BRIVIACT® demonstrated efficacy over placebo in reducing partial-onset seizure frequency during the treatment period.[1]

The most common adverse reactions occurring at a frequency of at least 5% in patients treated with BRIVIACT doses of at least 50 mg/day and greater than placebo were somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms. The discontinuation rate due to adverse events was 5%, 8%, and 7% for patients randomized to receive BRIVIACT® at the recommended doses of 50 mg, 100 mg, and 200 mg/day, respectively, compared to 4% in patients randomized to receive placebo.[1]

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 and Germany. UCB has submitted additional regulatory applications for brivaracetam in other countries including Australia, Brazil, Canada, 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® will be available in three formulations (film-coated tablets, oral solution, and injection).[1,4]

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.

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[5,6,7,8,9]

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) 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 8,500 people in approximately 40 countries, the company generated revenue of EUR 3.3 billion in 2014. 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.

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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.

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