UCB News

UCB's new epilepsy drug BRIVIACT® receives EU approval

- BRIVIACT® will offer greater treatment choice to physicians and patients, bringing hope to the millions of Europeans who suffer from epilepsy[1]
- It is estimated that more than 30% of the approximate 65 million people worldwide with epilepsy are resistant to treatments currently available[2,3]
- BRIVIACT® will join the UCB anti-epileptic drugs (AEDs) portfolio, further strengthening its leadership in epilepsy and commitment to improving the lives of people with the condition

Brussels (Belgium), 19 January 2016 – UCB today announced the European Commission (EC) has approved BRIVIACT® (brivaracetam) as an adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization (spreading to both sides of the brain after the initial seizure) in adult and adolescent patients from 16 years of age with epilepsy. BRIVIACT® treatment is initiated without titration, meaning patients receive a therapeutic dose of the drug from the first day of treatment.

"Today's approval from the European Commission is exciting news for those in the EU who suffer from epilepsy and need alternative treatment options," said Jean-Christophe Tellier, UCB's CEO. "One of UCB's key ambitions is improving the lives of people with epilepsy, and we are thrilled to bring BRIVIACT® to patients in Europe and lead the way in making positive changes in how epilepsy is managed."

First launches in EU countries are set to begin this quarter.

Epilepsy is a chronic neurological disorder affecting around 7 million people in Europe.[1] Despite currently-available treatments, many patients with epilepsy still experience seizures regardless of using at least one AED.[2]

"There is an unmet need for epilepsy medicines that effectively control seizures and are also well tolerated by patients," said Dr Manuel Toledo MD, PhD, consultant neurologist and epileptologist at the Vall d'Hebron Hospital, Barcelona, Spain, who participated in the placebo-controlled trials for BRIVIACT®. "A new treatment such as BRIVIACT®, that enables patients to receive a therapeutic dose from the very first day without titration, represents a big step forward to further helping people with epilepsy."

The EC approval is based on pooled data from three pivotal Phase 3 studies (N01252, N01253 and N01358), in which BRIVIACT® demonstrated statistically significant reductions over placebo in

partial-onset seizure frequency per 28 days (19.5%, 24.4% and 24.0% for BRIVIACT® 50, 100 and 200 mg/day respectively, p<0.01).[4,5] The proportion of patients showing a 50% or greater reduction in partial-onset seizure frequency was 34.2% (50 mg/day), 39.5% (100 mg/day) and 37.8% (200 mg/day), vs. 20.3% for placebo (p<0.01 for all arms).[4,5] BRIVIACT® was generally well tolerated by patients, and the most commonly reported adverse reactions (≥5%) with the drug were somnolence (15.2%), dizziness (11.2%), headache (9.6%) and fatigue (8.7%).[4] Brivaracetam is also currently under review for approval in other countries including the U.S., Australia, Canada and Switzerland.

About BRIVIACT®

Rationally designed and developed by UCB, BRIVIACT® is a selective high-affinity synaptic vesicle protein 2A ligand available in three formulations (film-coated tablets, oral solution and solution for injection/infusion).[6] BRIVIACT® can be initiated without titration, meaning patients receive a therapeutic dose of brivaracetam from the first day of treatment. Physicians are also able to adjust dosing up or down depending on patient response and tolerability.

Overall, the BRIVIACT® clinical development program has involved more than 3,000 people and more than eight years of experience for some patients.[7]

About epilepsy[1,3,8]

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide. Although epilepsy may be linked to factors such as health conditions, race and age, it can develop in anyone at any age. An estimated 7 million people in Europe will have an epileptic seizure at some time during their lives.

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 AEDs. As a company with 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.

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3. Epilepsy Foundation. Who gets epilepsy? Accessed 17 December 2015 from http://www.epilepsy.com/learn/epilepsy-101/who-gets-epilepsy.
4. Quarato, P., et al. Efficacy and safety of adjunctive brivaracetam for partial-onset (focal) seizures: pooled results from three fixed-dose, randomised, double-blind, placebo-controlled Phase III studies *Epilepsia*; 2015; 56; Suppl.1; 208-209. Abstract p0851 presented a 31st International Epilepsy Congress (IEC), September 05-09, 2015; Istanbul, Turkey.
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6. BRIVIACT® Summary of Product Characteristics.
7. UCB data on file.
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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 € 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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