UCB News

CHMP recommends EU approval for UCB's new drug brivaracetam for people with epilepsy

- CHMP recommendation based on Phase 3 data showing brivaracetam significantly reduced the frequency of seizures in patients aged 16 years and older with uncontrolled partial-onset seizures[1]
- Subject to European Commission approval, brivaracetam will be marketed as BRIVIACT®
- BRIVIACT will expand and strengthen UCB's epilepsy portfolio with an additional treatment option, offering greater choice to physicians and their patients

Brussels (Belgium), 20 November 2015 – UCB today announced the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for brivaracetam as adjunctive therapy for adult epilepsy patients (aged 16 years and older) with uncontrolled partial-onset seizures, marking an important milestone towards making it available to patients in the EU. Brivaracetam, UCB's latest antiepileptic drug (AED) candidate, will be marketed as BRIVIACT® once final approved by the European Commission.

"This CHMP positive opinion for brivaracetam represents a significant step forward to providing a new treatment option for epilepsy patients who cannot control their seizures with current antiepileptic drugs," said Jean-Christophe Tellier, Chief Executive Officer, UCB. "Over the years UCB has been building a leading expertise in epilepsy, working very closely with patients through all stages of development to ensure UCB scientists and physicians better understand the unmet needs of those suffering from this severe and complex chronic disease. We look forward to the European Commission's decision, and are hopeful that we are able to make brivaracetam available to patients as soon as possible to help improve the lives of those with epilepsy."

The CHMP's opinion is based on pooled data from three pivotal Phase 3 studies (N01252, N01253 and N01358), which showed brivaracetam demonstrated statistically significant reductions over placebo in partial-onset seizure frequency per 28 days (19.5%, 24.4% and 24.0% for brivaracetam 50, 100 and 200 mg/day respectively, $p<0.01$).[1,2] The proportion of patients showing a $\geq$50% or greater reduction in partial-onset seizure frequency was 34.2% (50 mg/day), 39.5% (100 mg/day) and 37.8% (200 mg/day), vs. 20.3% for placebo ($p<0.01$ for all arms).[1,2] Brivaracetam was generally well tolerated by patients, and the most commonly reported adverse events (≥5%) with the drug were somnolence (15.2%), dizziness (11.2%), headache (9.6%) and fatigue (8.7%).[1] Brivaracetam is also currently under review in other countries including the U.S., Australia, Canada and Switzerland.

With several anti-epileptic drugs in its portfolio, UCB has a strong heritage in epilepsy, a chronic neurological disorder affecting approximately 65 million people worldwide.[3] It is estimated that more than 30% of patients are resistant to treatments currently available,[4] and some patients with epilepsy still experience seizures despite using at least one AED.[5]

About brivaracetam

Rationally designed and developed by UCB, brivaracetam is a selective synaptic vesicle protein 2A ligand available in three formulations (film-coated tablets, oral solution and solution for injection/infusion). Brivaracetam can be initiated without titration, meaning patients can 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.[6]

Brivaracetam's clinical development program includes three Phase 3 studies evaluating the efficacy and safety of adjunctive brivaracetam in patients with uncontrolled partial-onset seizures.

Pooled results showed:[1,2,6]

- Brivaracetam demonstrated statistically significant percent reductions over placebo in partial-onset seizure frequency per 28 days (19.5% [n=161], 24.4% [n=332] and 24.0% [n=249] for 50, 100 and 200 mg/day, respectively, $p<0.01$)
- The $\geq$50% responder rate for brivaracetam 50, 100 and 200 mg/day was 34.2% (55/161), 39.5% (131/332) and 37.8% (94/249), compared with 20.3% (85/418) for placebo, $p<0.01$ for all dose arms. The odds ratios vs. placebo (95% confidence interval) were 2.15 (1.3,3.4), 2.56 (1.8,3.6) and 2.2.7 (1.5,3.3) for brivaracetam 50, 100 and 200 mg/day, respectively
- The most commonly reported adverse events (≥5%) for the combined brivaracetam groups (n=803) and the placebo group (n=459) were somnolence (15.2% vs. 8.5%), dizziness (11.2% vs. 7.2%), headache (9.6% vs. 10.2%) and fatigue (8.7% vs. 3.7%)

Overall, the brivaracetam clinical development program has involved more than 3,000 people and more than eight years of experience for some patients.[6]

About epilepsy[3,7,8]

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.

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 8500 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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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.