



Major advance in UCB pipeline: positive topline Phase 3 results for *brivaracetam* in epilepsy patients with partial-onset seizures

- *Brivaracetam* is the newest investigational medicine to emerge from UCB's rich late-stage pipeline
- Submissions to US and EU regulatory authorities planned for early 2015: subject to approval as adjunctive treatment for partial-onset seizures in adult epilepsy patients, *brivaracetam* would provide a new option for people with uncontrolled seizures
- *Brivaracetam* clinical development program has involved over 3,000 people and offers over 8 years of clinical experience with some patients¹

Brussels (Belgium), 23rd July 2014 – 0700 (CEST) – regulated information – UCB today announced an important advance in its research and development pipeline with positive topline results from the latest Phase 3 study with *brivaracetam*. This study was designed to evaluate the efficacy and safety of *brivaracetam* (100 and 200 mg/day, without titration) compared to placebo, as adjunctive treatment in adult focal epilepsy patients with partial-onset seizures, not fully controlled despite treatment with one or two concomitant antiepileptic drugs (AEDs).²

Results showed that *brivaracetam* reduced partial-onset seizure frequency and improved responder rates, both with statistical significance. The most commonly reported adverse events were somnolence, dizziness, fatigue and headache.³

“Today's positive results with *brivaracetam* represent a significant milestone in our strategy to deliver new treatment options for people with severe diseases. As the newest product to emerge from our late-stage pipeline, *brivaracetam* is leading the way for UCB's new era of patient-centric solutions,” said Jean-Christophe Tellier, CEO-Elect, UCB. “We are proud to provide AED options for the epilepsy community today, and remain committed to addressing the unmet needs of adult patients who continue to experience uncontrolled seizures.”

“The positive data from the most recent Phase 3 study demonstrated robust and clinically relevant seizure reduction in predominantly treatment resistant patients, and tolerability was consistent with previous *brivaracetam* trials,”⁴⁻⁶ said Professor Dr. Iris Loew Friedrich, Chief Medical Officer and Executive Vice President, UCB. “This study was the largest Phase 3 study conducted in epilepsy patients with partial-onset seizures. Overall, the *brivaracetam* development program has involved

over 3,000 people and offers over eight years of clinical experience with some patients.¹ We look forward to discussing the data with the regulatory authorities and the scientific community.”

Based on the results of the *brivaracetam* Phase 3 program, UCB plans to submit a New Drug Application to the US Food & Drug Administration (FDA) and a Marketing Authorization Application to the European Medicines Agency (EMA) in early 2015.

This Phase 3 study was a randomized, double-blind, placebo-controlled, multicentre, parallel-group study to evaluate the efficacy and safety of adjunctive *brivaracetam* (100 and 200 mg/day) compared to placebo, over a 12-week treatment period, in 768 randomized focal epilepsy patients (aged 16 to 80 years) with partial-onset seizures, not fully controlled despite treatment with one or two concomitant AEDs.^{2,7} The primary endpoint for the European regulatory authorities is the 50% responder rate for partial-onset seizure frequency compared with placebo, over the treatment period standardized to a 28-day duration. The primary endpoint for the FDA is the percent reduction over placebo for partial-onset seizure frequency, over the treatment period standardized to a 28-day duration.² Detailed data from this study will be submitted for presentation at upcoming epilepsy congresses and for publications in peer-reviewed journals.

About *brivaracetam* and the Phase 3 clinical development program

Discovered and developed by UCB, *brivaracetam* is a highly selective synaptic vesicle protein 2A ligand.^{8,9}

The phase 3 clinical development plan for *brivaracetam* consisted of the following studies:

N01252: an evaluation of the efficacy and safety/tolerability of adjunctive *brivaracetam* 20, 50, and 100 mg/day compared with placebo over 12 weeks, in 399 randomized patients (≥ 16 to 70 years) with partial-onset seizures not fully controlled despite treatment with 1-2 concomitant AEDs.⁴

N01253: an evaluation of the efficacy and safety/tolerability of adjunctive *brivaracetam* at doses of 5, 20, and 50 mg/day compared with placebo over 12 weeks, in 400 randomized patients (≥ 16 to 70 years) with partial-onset seizures, not fully controlled despite treatment with 1-2 concomitant AEDs.⁵

N01254: an evaluation of the safety and tolerability of adjunctive *brivaracetam* given at individualized tailored doses between 20 and 150 mg/day, compared with placebo over 16 weeks, in 480 randomized patients (≥ 16 to 70 years) with uncontrolled epilepsy (up to 20% could be patients with generalized epilepsy), not fully controlled despite treatment with 1-3 concomitant AEDs.⁶

N01358: an evaluation of the efficacy and safety of adjunctive *brivaracetam* 100 and 200 mg/day compared with placebo over 12 weeks in 768 randomized patients (≥ 16 to 80 years) with partial-onset

seizures, not fully controlled despite treatment with 1-2 concomitant AEDs.^{2,7}

About Epilepsy^{10,11,12}

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide. It 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.

Although epilepsy may be linked to factors such as health conditions, race and age, it can develop in anyone at any age, and approximately 1 in 26 people will develop epilepsy in their lifetime.

Partial seizures begin with an electrical discharge in one area of the brain. Different things can cause partial seizures, for example head injury, brain infection, stroke, tumour, and changes in the way an area of the brain was formed before birth, called cortical dysplasias. Many times, no known cause is found, but genetic factors may be important in some partial 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.

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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 € 3.4 billion in 2013. 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. 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.