



## UCB announces US and EU regulatory filings for the investigational antiepileptic drug *brivaracetam*

- Major milestone for *brivaracetam* is latest step towards UCB goal of extending treatment choices for adult epilepsy patients with uncontrolled partial-onset seizures

**Brussels (Belgium), 21<sup>st</sup> January 2015 – 0700 (CET)** – UCB today announced regulatory milestones in the US and the EU for its investigational antiepileptic drug *brivaracetam*. In the US, the Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for *brivaracetam* as adjunctive therapy for the treatment of partial-onset seizures in patients from 16 years of age with epilepsy, and in the EU, the European Medicines Agency has validated for review the Marketing Authorization Application (MAA) for *brivaracetam* in the same proposed indication. Acceptance for review indicates that the FDA and EMA have found the Company's submissions to be sufficiently complete to proceed.

“Today is a major milestone for *brivaracetam* and an exciting day for everyone at UCB who is committed to its development. It is also an important time for the clinicians and patients whose involvement in *brivaracetam* clinical trials has been so important in helping us to address the need for new treatment options for adult patients who do not achieve partial-onset seizure control with current antiepileptic drugs. We look forward to working closely with the FDA and EMA through the review process.” said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President UCB.

The US NDA and the EU MAA are supported by data from a comprehensive clinical development program including three Phase 3 studies which evaluated the efficacy and safety of adjunctive *brivaracetam* (5 mg-200 mg/day dose range) in patients with uncontrolled partial-onset seizures.<sup>1-3</sup> A supportive fourth Phase 3 study evaluated the safety and tolerability of adjunctive *brivaracetam* given at individualized tailored doses between 20 and 150 mg/day in adult patients with partial-onset seizures.<sup>4</sup>

Overall, the *brivaracetam* clinical development program has involved over 3000 people and over 8 years of experience for some patients.<sup>5</sup> There are six on-going studies of *brivaracetam*.<sup>6-11</sup> These are predominantly open-label, follow-up studies to assess long-term safety and efficacy of *brivaracetam*. Discovered and developed by UCB, *brivaracetam* is a selective synaptic vesicle protein 2A ligand.<sup>12,13</sup>

## NOTES TO EDITORS

### About Epilepsy<sup>14,15,16</sup>

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

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.

### 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.

### For further information

#### Corporate Communications

France Nivelles,  
Global Communications, UCB

T +32.2.559.9178,  
france.nivelles@ucb.com

Laurent Schots,  
Media Relations, UCB

T+32.2.559.92.64,  
Laurent.schots@ucb.com

#### Investor Relations

Antje Witte,  
Investor Relations, UCB

T +32.2.559.94.14,  
antje.witte@ucb.com

#### Brand Communications

Eimear O'Brien,  
Global Brand Communications, UCB

T +32 2 559 92 71,  
eimear.obrien@ucb.com

Andrea Levin  
US Public Relations & Communications, UCB

T+1 770 970 8352  
Andrea.Levin@ucb.com

## References

1. Ryvlin, P., *et al.*, Adjunctive brivaracetam in adults with uncontrolled focal epilepsy: results from a double-blind, randomized, placebo-controlled trial. *Epilepsia*, 2014. 55(1):47-56.
2. Biton, V., *et al.*, Brivaracetam as adjunctive treatment for uncontrolled partial epilepsy in adults: a phase III randomized, double-blind, placebo-controlled trial. *Epilepsia*, 2014. 55(1): 57-66.
3. Klein P *et al.* A Randomized, Double-blind, Placebo-controlled, Multicenter, Parallel-group Study to Evaluate the Efficacy and Safety of Brivaracetam in Patients with Partial Onset Seizures. Abstract Presented at the 68<sup>th</sup> Annual Meeting of the American Epilepsy Society, Seattle, WA, December 5-9, 2014
4. Kwan, P., *et al.*, Adjunctive brivaracetam for uncontrolled focal and generalized epilepsies: results of a phase III, double-blind, randomized, placebo-controlled, flexible-dose trial. *Epilepsia*, 2014. 55(1):38-46.
5. UCB Data on File
6. N01379 Clinical Trials.gov identifier NCT01339559. An Open-label, Multicenter, Follow-up Study to Evaluate the Long-term Safety and Efficacy of Brivaracetam Used as Adjunctive Treatment in Subjects Aged 16 Years or Older With Epilepsy. Accessed 23rd November 2014 from: <http://clinicaltrials.gov/ct2/show/NCT01339559> .
7. N01372 Clinical Trials.gov identifier NCT01728077. An Open-label, Multicenter, Follow-up Study to Evaluate the Long-term Safety and Efficacy of Brivaracetam Used as Adjunctive Treatment in Subjects Aged 16 Years or Older With Epilepsy Phase 3b. Accessed 23rd November 2014 from <http://clinicaltrials.gov/ct2/show/NCT01728077>
8. N01315 Clinical Trials.gov identifier NCT00761774. An Open-label, Multinational, Multicenter, Follow-up Study to Evaluate the Long-term Safety and Efficacy of Brivaracetam Used at a Flexible Dose up to a Maximum of 200 mg/Day in Subjects Aged 16 Years or Older Suffering From Epilepsy. Accessed 23rd November 2014 from: <http://clinicaltrials.gov/ct2/show/NCT00761774>
9. N01266 Clinical Trials.gov identifier NCT01364597. Open-label, Single-arm, Multicenter, Long-term Study to Evaluate Safety and Efficacy of Brivaracetam Used as Adjunctive Treatment in Pediatric Subjects With Epilepsy. Accessed 23rd November 2014 from: <http://clinicaltrials.gov/ct2/show/NCT01364597> .
10. N01199 Clinical Trials.gov identifier NCT00150800. An Open-label, Multi-center, Follow-up Trial to Evaluate Long Term Safety and Efficacy of Brivaracetam Used as Adjunctive Treatment at a Flexible Dose up to a Maximum of 200 mg/Day in Subjects Aged 16 Years or Older Suffering From Epilepsy. Accessed 23rd November 2014 from: <http://clinicaltrials.gov/show/NCT00150800> .
11. N01125 Clinical Trials.gov identifier NCT00175916. An Open-label, Multicenter, Follow-up Trial to Evaluate Long-term Safety and Efficacy of Brivaracetam Used as Adjunctive Treatment at a Flexible Dose up to a Maximum of 200 mg/Day in Subjects Aged 16 Years or Older Suffering From Epilepsy. Accessed 23rd November 2014 from: <http://clinicaltrials.gov/ct2/show/NCT00175916>
12. Kenda, B.M., *et al.*, Discovery of 4-Substituted Pyrrolidone Butanamides as New Agents with Significant Antiepileptic Activity. *Journal of Medicinal Chemistry*, 2004. 47(3): 530-549.
13. Gillard, M., *et al.*, Binding characteristics of brivaracetam, a selective, high affinity SV2A ligand in rat, mouse and human brain: relationship to anti-convulsant properties. *Eur J Pharmacol*, 2011. 664(1-3): 36-44
14. Fisher, R.S., *et al.*, ILAE Official Report: A practical clinical definition of epilepsy. *Epilepsia*, 2014. 55(4): 475-482
15. Institute of Medicine. *Epilepsy Across the Spectrum. Promoting Health and Understanding*, Washington, DC: The National Academic Press, 2012 brief report. Accessed 29th October 2014 from [http://www.iom.edu/~media/Files/Report%20Files/2012/Epilepsy/epilepsy\\_rb.pdf](http://www.iom.edu/~media/Files/Report%20Files/2012/Epilepsy/epilepsy_rb.pdf)
16. The Epilepsy Foundation of America. Who gets epilepsy? Accessed 29th October 2014 from <http://www.epilepsy.com/learn/epilepsy-101/who-gets-epilepsy>

## 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 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.