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Data presented at the American Academy of Neurology Meeting demonstrated long-term efficacy and tolerability of Vimpat[®] (lacosamide)

- Long-term data presented for lacosamide demonstrated sustained efficacy for up to three years¹
- Long-term safety and tolerability for a median duration of 2 years showed a consistent profile to that from short-term studies^{1,2}

Brussels (Belgium), 15 April 2010 – 1430 CET - press release – UCB's antiepileptic drug (AED) Vimpat[®] (lacosamide) featured in several studies and analyses presented at the 62nd annual American Academy of Neurology (AAN) meeting. These data offer additional clinical evidence supporting the use of lacosamide as adjunctive therapy in the treatment of adult patients with partial-onset seizures. Research presented at the meeting demonstrated sustained efficacy in adult patients taking lacosamide for up to three years, and a consistent long-term safety and tolerability profile (median duration of two years) when compared to that from short-term trials.^{1,2}

In Europe, Vimpat[®] (film-coated tablets, syrup, and solution for infusion) is approved as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy, aged 16 years and older.³ Vimpat[®] is approved in the U.S. as an add-on therapy for the treatment of partial-onset seizures in people with epilepsy who are 17 years and older, and is available as oral tablets and as an intravenous (IV) injection.⁴ Vimpat[®] injection may be used when oral administration is temporarily not feasible. Vimpat[®] has a novel mechanism of action that is different from all currently available AEDs, although the precise mechanism by which Vimpat[®] exerts its antiepileptic effect in humans is yet to be fully elucidated.³



Summary of Long-term Lacosamide Data Presented at 2010 AAN Annual Meeting

Abstract: Long-term Efficacy of Lacosamide for Partial-Onset Seizures: An Interim Evaluation of Completer Cohorts Exposed to Lacosamide for up to 36 Months¹

This analysis of phase II/III double-blind and/or open-label extension trials demonstrated that lacosamide produced long-term, sustained efficacy in cohorts of patients with partial-onset seizures who completed 12, 24, and 36 months of treatment.

- The reduction in seizure frequency associated with lacosamide was sustained across all exposure-duration cohorts, as was the proportion of responders – patients who experienced a 50 or 75 percent or greater reduction in seizures compared with baseline:
 - The median percent reduction in seizure frequency for the first 3 months of treatment was 45.2 percent, 48.2 percent, and 46.5 percent for the 12, 24, and 36 month cohort, respectively.
 - The median percent reduction for the last 3 months of treatment was 51.3 percent, 65.9 percent, and 59.7 percent for each cohort, respectively.
 - Responder rates were also sustained over time in each cohort:
 - Across the three exposure-duration cohorts, 44.2 percent to 47.7 percent of patients reported a 50 percent or greater reduction in seizures during the first 3 months of treatment, compared with 51.6 percent to 60.5 percent for the last 3 months of treatment.
 - 18.6 percent to 20.4 percent of patients reported a 75 percent or greater reduction in seizures during the first 3 months of treatment, compared with 29.5 percent to 37.0 percent for the last 3 months.

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm, Room 808 (Abstract P05.179)

Elinor Ben-Menachemⁱ, Jacqueline Frenchⁱⁱ, Jouko Isojarviⁱⁱⁱ, David Hebertⁱⁱⁱ, Pamela Dotyⁱⁱ

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Abstract: Long-term Safety and Tolerability of Lacosamide for Partial-Onset Seizures: An Interim Evaluation of Patients Exposed to Lacosamide in Double-Blind and Open Label Trials²

This analysis of 1,327 patients exposed to lacosamide during double-blind or open-label extension trials demonstrated that the incidence of adverse events, as well as vital signs and clinical laboratory and ECG findings, among patients taking lacosamide for a median duration of 700 days, or almost 2 years (range: 1 day to 2,437 days, or 6.7 years), were



similar to those reported with short-term use. The most commonly used dose was 400 mg/day.

- No new types of TEAEs judged by researchers to be related to lacosamide emerged with long-term use.
- The most common TEAEs (greater than or equal to 10 percent) reported at any time during the double-blind and open-label extension trials were dizziness (45.6 percent), headache (20.6 percent), diplopia (18.5 percent), nausea (15.3 percent), nasopharyngitis (14.3 percent), vomiting (14.1 percent), fatigue (13.8 percent), abnormal coordination (12.5 percent), blurred vision (12.0 percent), tremor (11.5 percent), somnolence (11.5 percent), convulsion (11.4 percent), and contusion (10.4 percent).
- Long-term lacosamide treatment was not associated with any clinically relevant changes in median or mean measurements for body weight, hematology, clinical chemistry, or vital signs. A small increase in mean PR interval (5-9ms) was observed. There were no reports of higher-degree heart block (i.e., second or third-degree).

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm, Room 808 (Abstract P05.181)

William Rosenfeld,ⁱ Felix Rosenow,ⁱⁱ Jouko Isojarvi,ⁱⁱⁱ David Hebert,ⁱⁱⁱ Pamela Dotyⁱⁱⁱ

ⁱThe Comprehensive Epilepsy Care Center for Children and Adults, St. Louis, Missouri;

ⁱⁱInterdisciplinary Epilepsy Center, Department of Neurology, Philipps-University, Marburg, Germany; ⁱⁱⁱSCHWARZ BIOSCIENCES (a member of the UCB Group), Raleigh, North Carolina

Other UCB-supported Vimpat[®] studies presented at the AAN meeting include:

- Lacosamide Efficacy in Partial-Onset Seizures with and without Secondary Generalization: A pooled Analysis of Three Phase II/III Trials

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm, Room 808 (Abstract P05.186)

Jouko Isojarvi, Felix Rosenow, R.E. Faught, David Herbert, Pamela Doty

- Pharmacokinetic evaluation of intravenous lacosamide as short-term replacement for oral lacosamide in partial-onset seizures

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm, Room 808 (Abstract P05.182)

Willi Cawello, PhD, Gregory Krauss, MD, Melissa Brock, PharmD, Andrea Eggert-Formella PharmD, BCPP



- [A Multicenter, Open-Label Trial to Assess the Safety And Tolerability of a Single Intravenous Loading Dose of Lacosamide Followed by Oral Maintenance as Adjunctive Therapy in Subjects with Partial-Onset Seizures: An Interim Report](#)

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm, Room 808 (Abstract P05.178)

Nathan B. Fountain, Gregory Krauss, Jouko Isojarvi, Deanne Dilley, Pamela Doty, David Rudd

- [Improvement in patient-reported outcomes seen in patients responding to lacosamide: pooled QOLIE-31, SSQ and PGIC data from Phase II/III clinical trials](#)

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm, Room 808 (Abstract P05.187)

Joyce A. Cramer, Christine De La Loge, Simon Borghs, Knut Mueller, Andrea Eggert-Formella, Pamela Doty

- [Outcome of Infants with Prenatal Exposure to Lacosamide During the Clinical Development Program](#)

Poster Session V: Epilepsy Therapy: Antiepileptic Drugs, Thursday, April 15, 7:30 am – 12:00 pm (Abstract P05.180)

Jouko Isojarvi, Christina Williams, Pamela Doty

Important safety information about Vimpat® in Europe³

Vimpat® is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy aged 16 years and older. Vimpat® solution for infusion is an alternative for patients when oral administration is temporarily not feasible. Contraindications: Hypersensitivity to the active substance or to peanuts or soya or to any of the excipients (tablet formulation only); known second- or third-degree atrioventricular (AV) block. Special warnings and precautions for use: Treatment with lacosamide has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine. Prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure. Caution should especially be exerted when treating elderly patients as they may be at an increased risk of cardiac disorders or when lacosamide is used in combination with products known to be associated with PR prolongation. Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents. Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. Undesirable effects: The most common



adverse reactions (greater than 10 percent) are dizziness, headache, diplopia, and nausea. Other common adverse reactions (1–10 percent) are depression, balance disorder, coordination abnormal, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, vision blurred, vertigo, vomiting, constipation, flatulence, pruritus, gait disturbance, asthenia, fatigue, fall, and skin laceration. Refer to the European Summary of Product Characteristics for full prescribing information.

<http://www.emea.europa.eu/humandocs/PDFs/EPAR/vimpat/emea-combined-h863en.pdf>
(Accessed 24.03.10)

Important safety information about Vimpat® in the U.S. ⁴

AEDs increase the risk of suicidal behavior and ideation. Patients taking Vimpat® should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Patients should be advised that Vimpat® may cause dizziness, ataxia, and syncope.

Caution is advised for patients with known cardiac conduction problems, who are taking drugs known to induce PR interval prolongation, or with severe cardiac disease. In patients with seizure disorders, Vimpat® should be gradually withdrawn to minimize the potential of increased seizure frequency. Multiorgan hypersensitivity reactions have been reported with antiepileptic drugs. If this reaction is suspected, treatment with Vimpat® should be discontinued.

The most common adverse reactions occurring in >10 percent of Vimpat®-treated patients, and greater than placebo, were dizziness, headache, nausea, and diplopia.

Dosage adjustments are recommended for patients with mild or moderate hepatic impairment or severe renal impairment. Use in severe hepatic impairment patients is not recommended.

Vimpat® is a Schedule V controlled substance.

Please see full prescribing information at <http://www.vimpat.com/pdfs/PI.pdf>. [Accessed 28th March 2010]

Vimpat® is not approved or available in Canada

Vimpat® is a registered trademark under license from Harris FRC Corporation.

For further information

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Onsite at meeting

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 9 000 people in over 40 countries, UCB produced revenue of EUR 3.1 billion in 2009. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.

References

1. Ben-Menachem E, French J, Isojarvi J, Hebert D, Doty P. Abstract: Long-term Efficacy of Lacosamide for Partial-Onset Seizures: An Interim Evaluation of Completer Cohorts Exposed to Lacosamide for up to 36 Months. Poster presented at American Academy of Neurology. Toronto, Canada, 2010.
2. Rosenfeld W, Rosenow F, Isojarvi J, Hebert D, Doty P. Abstract: Long-term Safety and Tolerability of Lacosamide for Partial-Onset Seizures: An Interim Evaluation of Patients Exposed to Lacosamide in Double-Blind and Open Label Trials. Poster presented at American Academy of Neurology. Toronto, Canada, 2010.
3. Vimpat® European Summary of Product Characteristics
<http://www.emea.europa.eu/humandocs/PDFs/EPAR/vimpat/emea-combined-h863en.pdf> (Accessed 24.03.10)
4. Vimpat® US Prescribing Information
<http://www.vimpat.com/pdfs/PI.pdf>.