New syrup formulation of Vimpat® (lacosamide) available for prescribing in the UK

Vimpat® (lacosamide) is now available in three formulations: oral solution, oral tablets and solution for infusion

Syrup formulation will be of use to people with epilepsy who have difficulty swallowing and may find that a liquid formulation meets their needs for add-on treatment of partial onset seizures

Syrup formulation offers added flexibility of treatment for both patients and prescribers

Slough, UK, April 10th 2012: UCB today announced the availability of Vimpat® (lacosamide) 10mg/ml syrup formulation for the adjunctive treatment of partial onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy.1

“Bringing lacosamide back to market in a third formulation highlights UCB’s commitment to providing a wide range of treatment options to people living with epilepsy,” said Dr Matthew Hickling, Associate Medical Director, Epilepsy at UCB. He added, “There are many people who find swallowing pills difficult and the syrup will help adults with swallowing difficulties.”

Lacosamide syrup solution 10 mg/mL is a clear, colorless to yellow-brown, strawberry-flavoured liquid. It should not be refrigerated.1

The efficacy of lacosamide as adjunctive therapy at recommended doses (200 mg/day, 400 mg/day) was established in 3 multicenter, randomized, placebo-controlled clinical trials with a 12-week maintenance period. These trials, involving 1308 patients with a history of an average of 23 years of partial-onset seizures, were designed to evaluate the efficacy and safety of lacosamide when administered concomitantly with 1-3 antiepileptic drugs in patients with uncontrolled partial-onset seizures with or without secondary generalisation. Overall the proportion of subjects with a 50% reduction in seizure frequency was 23%, 34%, and 40% for placebo, lacosamide 200 mg/day and lacosamide 400 mg/day, respectively.1

The most common adverse reactions reported in pivotal trials and occurring in 10 percent or more of lacosamide-treated patients, and greater than placebo, were dizziness, headache, nausea, and diplopia. Additional important safety information for lacosamide is available at the end of the press release.1

Lacosamide is now conveniently available in three formulations: oral tablets, oral solution and solution for infusion, ensuring that patients can maintain consistent lacosamide treatment in any clinical setting.

For further Information:
Scott Fleming, Head of UK Communications
T: 07702777378
E: scott.fleming@ucb.com
About Vimpat

Vimpat® (film-coated tablets, solution for infusion and syrup) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy. Vimpat® solution for infusion may be used when oral administration is temporarily not feasible.¹

The active substance, lacosamide (R-2-acetamido-N-benzyl-3-methoxypropionamide) is a functionalised amino acid.¹

Important safety information about Vimpat® in the EU and EEA

Vimpat® (film-coated tablets, solution for infusion and syrup) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy. Vimpat® solution for infusion may be used when oral administration is temporarily not feasible. Contraindications: Hypersensitivity to the active substance or any of the excipients; 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. Second-degree or higher AV block has been reported in post-marketing experience. In the placebo-controlled trials of lacosamide in epilepsy patients, atrial fibrillation or flutter were not reported; however, both have been reported in open-label epilepsy trials and in post-marketing experience. Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheadedness and fainting) and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath). Patients should be counseled to seek medical advice should any of these symptoms occur. Suicidal ideation and behavior have been reported in patients treated with antiepileptic agents. Therefore patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge. The solution for infusion contains sodium, which should be taken into consideration for patients on a controlled sodium diet. Effects on ability to drive and use machines: Lacosamide may have minor to moderate influence on the ability to drive and use machines. Lacosamide treatment has been associated with dizziness or blurred vision. Accordingly patients should be advised not to drive a car or to operate other potentially hazardous machinery until they are familiar with the effects of lacosamide on their ability to perform such activities. Laboratory abnormalities: Abnormalities in liver function tests have been observed in controlled trials with lacosamide in adult patients with partial-onset seizures who were taking 1-3 concomitant antiepileptic drugs. Elevations of ALT to ≥3XULN occurred in 0.7% (7/935) of lacosamide patients and 0% (0/356) of placebo patients. Multiorgan Hypersensitivity Reactions: Multiorgan hypersensitivity reactions have been reported in patients treated with some antiepileptic agents. These reactions are variable in expression but typically present with fever and rash and can be associated with involvement of different organ systems. Potential cases have been reported rarely with lacosamide and if multiorgan hypersensitivity reaction is suspected, lacosamide should be discontinued. Undesirable effects: The most common adverse reactions (≥10%) are dizziness, headache, diplopia, and nausea. Other common adverse reactions (≥1%-<10%) are depression, confusional state, insomnia, balance disorder, coordination abnormal, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, injection site pain or discomfort (specific to solution for infusion), fall, and skin laceration.¹ Refer to the Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: February 2012.

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 8,000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statements: UCB

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.

References
1. Vimpat Summary of product characteristics. Date of revision February 2012. Available at www.medicines.org.uk/EMC/medicine/21158/SPC/Vimpat+50+mg%2c+100+mg%2c+150+mg+%26+200+mg+film-coated+tablets%2c+10+mg+ml+syrup+and+10+mg+ml+solution+for+infusion/