

UCB's VIMPAT® (lacosamide) CV now approved by FDA in U.S. for primary generalized tonic-clonic seizures and expanded pediatric use for people living with epilepsy

- New approval for VIMPAT® (lacosamide) CV in the U.S. as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in patients four years of age and older
- All three VIMPAT formulations, including injection for intravenous use, are now indicated for the treatment of partial-onset seizures and as adjunctive therapy in the treatment of PGTCS in patients four years of age and older
- These approvals further help patients with epilepsy who may have had limited treatment options in the past, while reinforcing UCB's leadership in transforming epilepsy care
- In October, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for VIMPAT as adjunctive therapy in the treatment of PGTCS in adults, adolescents and children from four years of age with idiopathic generalized epilepsy

Brussels, Belgium, Atlanta, Ga., November 17, 2020: UCB, a global pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved VIMPAT® (lacosamide) CV as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in patients four years of age and older and VIMPAT injection for intravenous use in children four years of age and older.¹ PGTCS is a type of seizure that occurs all over the brain, affecting both sides of the brain from the start, causing muscles to stiffen and convulsions to occur for up to a few minutes.²

"These approvals underscore UCB's commitment to people living with epilepsy and our focus on finding solutions for specific unmet needs within the epilepsy community," said Mike Davis, Head of U.S. Neurology at UCB. "We are pleased that VIMPAT is now available as a treatment option for people living with primary generalized tonic-clonic seizures on their journey to seizure control."

The PGTCS approval is based, in part, on results of a Phase 3 study recently published in the *Journal of Neurology, Neurosurgery & Psychiatry*.³ Adjunctive treatment with VIMPAT resulted in a significantly lower risk of developing a second PGTCS during the 24-week treatment period, with the corresponding risk reduction being 45% (p=0.001), and a significantly higher rate of freedom from PGTCS during the treatment period compared with placebo (31.3% vs 17.2%, p=0.011).¹

People living with generalized tonic-clonic seizures have an increased risk of injury⁴ and those who experienced three or more in one year had a fifteen-fold increased risk of sudden unexpected death in epilepsy.⁵

"The treatment of primary generalized tonic-clonic (convulsive) seizures is challenging, with about one-third of patients still being refractory while on therapy," said David Vossler, MD, FAAN FACNS FAES, Department of Neurology, University of Washington, Seattle, USA. "Bolstered by a wealth of data demonstrating VIMPAT's efficacy and safety, this new indication gives people suffering from PGTCS a chance at freedom from these seizures, which many have never experienced."

Results from the Phase 3 study showed that VIMPAT was generally tolerated in patients with idiopathic generalised epilepsy (IGE) and PGTCS. The most common adverse reactions (≥10%) reported in patients treated with VIMPAT were dizziness (23%), somnolence (17%), headache (14%), and nausea (10%) compared to 7%, 14%, 10%, and 6%, respectively, of patients who received placebo.¹

Regarding the expanded pediatric population, VIMPAT tablets and oral solution were already approved to treat partial-onset seizures in adults and children four years and older as monotherapy and adjunctive therapy. In the US, VIMPAT injection was previously approved for the treatment of partial-onset seizures only in adult patients (17 years of age and older).

In Europe VIMPAT is currently not indicated in patients with PGTCs, however, in October 2020, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for VIMPAT as adjunctive therapy in the treatment of PGTCs in adults, adolescents and children from four years of age with idiopathic generalized epilepsy.⁶ Regulatory reviews for use of VIMPAT in the treatment of PGTCs are also underway in the Japan and Australia.

About Epilepsy

Epilepsy is the main symptom of a variety of chronic disorders of the brain. It is the fourth most common neurological condition worldwide and affects approximately 65 million people. Anyone can develop epilepsy; it occurs across all ages, races and genders, and is defined as one or more unprovoked epileptic seizures with a risk of further seizures.⁷

About UCB in Epilepsy

UCB has a rich heritage in epilepsy with over 20 years of experience in the research and development of anti-epileptic 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.

About UCB

UCB, Brussels, Belgium (www.ucb-usa.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 the central nervous system. With more than 7,600 people in approximately 40 countries, the company generated revenue of €4.9 billion in 2019. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCBUSA.

About VIMPAT® (lacosamide) CV in the U.S.¹

VIMPAT® was approved in the U.S. in 2008 as an add-on therapy for the treatment of partial-onset seizures in adult patients with epilepsy. VIMPAT was approved as monotherapy for adults in August 2014, and as monotherapy or adjunctive therapy in patients four years of age and older with partial-onset seizures in 2017. VIMPAT is available in three formulations: oral tablets, oral solution, and intravenous (IV) injection.

INDICATION

VIMPAT® is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. VIMPAT is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including VIMPAT, increase the risk of suicidal behavior and ideation. Monitor patients taking VIMPAT for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to the healthcare provider.
- **Dizziness and Ataxia:** VIMPAT may cause dizziness and ataxia in adult and pediatric patients. In adult clinical trials for partial-onset seizures, the onset of dizziness and ataxia was most commonly observed during titration. Advise patients not to drive, operate complex machinery, or engage in other hazardous activities until they are familiar with the effects of VIMPAT on their ability to perform such activities.
- **Cardiac Rhythm and Conduction Abnormalities**

PR Interval Prolongation, Atrioventricular Block, and Ventricular Tachyarrhythmia

Dose-dependent prolongations in PR interval with VIMPAT have been observed in clinical studies in adult patients and in healthy volunteers. When VIMPAT is given with other drugs that prolong the PR interval,



Inspired by patients.
Driven by science.

further PR prolongation is possible.

In the postmarketing setting, there have been reports of cardiac arrhythmias in patients treated with VIMPAT, including bradycardia, AV block, and ventricular tachyarrhythmia, which have rarely resulted in asystole, cardiac arrest, and death. Most, although not all, cases have occurred in patients with underlying proarrhythmic conditions, or in those taking concomitant medications that affect cardiac conduction or prolong the PR interval. These events have occurred with both oral and intravenous routes of administration and at prescribed doses as well as in the setting of overdose.

VIMPAT should be used with caution in patients with underlying proarrhythmic conditions such as known cardiac conduction problems (e.g., marked first-degree AV block, second-degree or higher AV block, and sick sinus syndrome without pacemaker), severe cardiac disease (such as myocardial ischemia or heart failure, or structural heart disease), and cardiac sodium channelopathies (e.g., Brugada Syndrome). VIMPAT should also be used with caution in patients on concomitant medications that affect cardiac conduction, including sodium channel blockers, beta-blockers, calcium channel blockers, potassium channel blockers, and medications that prolong the PR interval. In such patients, obtaining an ECG before beginning VIMPAT, and after VIMPAT is titrated to steady-state maintenance dose, is recommended. In addition, these patients should be closely monitored if they are administered VIMPAT through the intravenous route. Patients should be made aware of and report cardiac signs or symptoms to their healthcare provider right away.

Atrial Fibrillation and Atrial Flutter

VIMPAT administration may predispose to atrial arrhythmias (atrial fibrillation or flutter), especially in patients with diabetic neuropathy and/or cardiovascular disease.

- **Syncope:** VIMPAT may cause syncope in adult and pediatric patients.
- **Withdrawal of Antiepileptic Drugs:** Gradually withdraw VIMPAT (over a minimum of 1 week) to minimize the potential of increased seizure frequency.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** Also known as multi-organ hypersensitivity, has been reported with antiepileptic drugs, including VIMPAT. Some of these events have been fatal or life-threatening. If signs or symptoms are present, immediately evaluate the patient. Discontinue VIMPAT if an alternative etiology for the signs and symptoms cannot be established.
- **Risks in Patients with Phenylketonuria:** VIMPAT oral solution contains aspartame, a source of phenylalanine, which can be harmful in patients with phenylketonuria (PKU). A 200 mg dose of VIMPAT oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.

Adverse Reactions

- **Partial-Onset Seizures:** In the adult adjunctive therapy placebo-controlled clinical trials for partial-onset seizures, the most frequently seen adverse reaction with VIMPAT was dizziness (31% vs 8% placebo). Other common adverse reactions occurring in ≥ 10 percent of VIMPAT-treated patients, and greater than placebo, were headache, nausea, and diplopia. In the adult monotherapy clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo-controlled trials, with the exception of insomnia (observed at a higher rate of $\geq 2\%$).
- **Primary Generalized Tonic-Clonic Seizures:** In the adjunctive therapy placebo-controlled trial for primary generalized tonic-clonic seizures, the adverse reactions were generally similar to those that occurred in the partial-onset seizure placebo-controlled trials. The adverse reactions most commonly reported were dizziness, somnolence, headache, and nausea.
- **Pediatric patients:** Adverse reactions reported in clinical studies of pediatric patients 4 to less than 17 years of age were similar to those seen in adult patients.
- **Injection:** In adult adjunctive therapy clinical trials for partial-onset seizures, adverse reactions with intravenous administration generally were similar to those that occurred with the oral formulation, although intravenous administration was associated with local adverse reactions such as injection site

pain or discomfort (2.5%), irritation (1%), and erythema (0.5%). When administering a loading dose, the incidence of CNS adverse reactions, such as dizziness, somnolence, and paresthesia, may be higher with 15-minute administration than over a 30- to 60-minute period. The adverse reactions associated with VIMPAT injection in adult patients with primary generalized tonic-clonic seizures are expected to be similar to those seen in adults with partial-onset seizures. The adverse reactions associated with VIMPAT injection in pediatric patients are expected to be similar to those noted in adults. Infusion times less than 30 minutes were not adequately studied in pediatric patients.

VIMPAT is a Schedule V controlled substance.

[Please refer to full Prescribing Information.](#)

Full Prescribing Information links to: <https://www.ucb-usa.com/vimpat-prescribing-information.pdf>

About VIMPAT® in the EU

VIMPAT® was first launched in the European Union in September 2008, as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy.

In countries of the EU, VIMPAT® is available as film-coated tablets, syrup and solution for infusion. Lacosamide solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

Important Safety Information about VIMPAT® in the EU and EEA⁸

VIMPAT® is indicated as monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. VIMPAT® therapy can be initiated with either oral or IV administration. For the paediatric population, the physician should prescribe the most appropriate formulation and strength according to weight and dose. A single loading dose may be initiated in patients in situations when the physician determines that rapid attainment of lacosamide steady state plasma concentration and therapeutic effect is warranted. It should be administered under medical supervision with consideration of the potential for increased incidence of serious cardiac arrhythmia and CNS adverse reactions. Administration of a loading dose has not been studied in acute conditions such as status epilepticus. Use of a loading dose is not recommended in adolescents and children weighing less than 50 kg. Administration of a loading dose has not been studied in children. A maximum dose of 300 mg/day is recommended for paediatric patients with mild to moderate hepatic impairment weighing 50 kg or more and for adult patients with mild to moderate hepatic impairment as well. Based on data in adults, in paediatric patients weighing less than 50 kg with mild to moderate hepatic impairment, a reduction of 25 % of the maximum dose should be applied. Lacosamide should be administered to adult and paediatric patients with severe hepatic impairment only when the expected therapeutic benefits are anticipated to outweigh the possible risks. The dose may need to be adjusted while carefully observing disease activity and potential side effects in the patient. In adolescents and adults weighing 50 kg or more with mild to moderate hepatic impairment a loading dose of 200mg may be considered, but further dose titration (>200 mg daily) should be performed with caution. In paediatric patients weighing 50 kg or more and in adult patients with mild or moderate renal impairment a loading dose of 200 mg may be considered, but further dose titration (> 200 mg daily) should be performed with caution. In paediatric patients weighing 50 kg or more and in adult patients with severe renal impairment (CLCR \leq 30 ml/min) or with end-stage renal disease, a maximum dose of 250 mg/day is recommended and the dose titration should be performed with caution. In paediatric patients weighing less than 50 kg with severe renal impairment (CLCR \leq 30 ml/min) and in those with end-stage renal disease, a reduction of 25 % of the maximum dose is recommended. 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 VIMPAT® 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. Dose-related prolongations in PR interval with VIMPAT® have been observed in clinical studies. VIMPAT® should be used with caution in patients with underlying proarrhythmic conditions such as patients with

known cardiac conduction problems or severe cardiac disease (e.g. myocardial ischaemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products, as well as in elderly patients. In these patients it should be considered to perform an ECG before a Vimpat dose increase above 400mg/day and after Vimpat is titrated to steady-state. In the placebo-controlled trials of VIMPAT® 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. In post-marketing experience, AV block (including second degree or higher AV block) has been reported. In patients with proarrhythmic conditions, ventricular tachyarrhythmia has been reported. In rare cases, these events have led to asystole, cardiac arrest and death in patients with underlying proarrhythmic conditions. Patients should be made aware of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting). Patients should be counselled to seek immediate medical advice if these symptoms occur. Suicidal ideation and behaviour have been reported in patients treated with antiepileptic medicinal products in several indications. 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. The safety and efficacy of lacosamide in paediatric patients with epilepsy syndromes in which focal and generalised seizures may coexist have not been determined. VIMPAT® syrup contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed). Vimpat Syrup contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. Vimpat syrup contains propylene glycol (E1520). VIMPAT® syrup contains 1.42 mg sodium per ml, equivalent to 0.07 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. VIMPAT® solution for infusion contains 59.8 mg sodium per vial, equivalent to 3% of the WHO recommended maximum daily intake of 2 g sodium for an adult. Effects on ability to drive and use machines: VIMPAT® may have minor to moderate influence on the ability to drive and use machines. VIMPAT® 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 VIMPAT® on their ability to perform such activities. Undesirable effects: The most common adverse reactions ($\geq 10\%$) are dizziness, headache, diplopia, and nausea. They were usually mild to moderate in intensity. Some were dose-related and could be alleviated by reducing the dose. Incidence and severity of CNS and gastrointestinal (GI) adverse reactions usually decreased over time. Incidence of CNS adverse reactions such as dizziness may be higher after a loading dose. Other common adverse reactions ($\geq 1\%$ - $< 10\%$) are depression, confusional state, insomnia, balance disorder, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, paraesthesia, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, diarrhoea, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, feeling drunk, injection site pain or discomfort (local adverse events associated with intravenous administration), irritation (local adverse events associated with intravenous administration), fall, and skin laceration, contusion. The use of VIMPAT® is associated with dose-related increase in the PR interval. Adverse reactions associated with PR interval prolongation (e.g. atrioventricular block, syncope, bradycardia) may occur. The safety profile of lacosamide in placebo-controlled and in open-label studies (n=408) in adjunctive therapy in children from 4 years of age was consistent with the safety profile observed in adults although the frequency of some adverse reactions (somnolence, vomiting and convulsion) was increased and additional adverse reactions (nasopharyngitis, pyrexia, pharyngitis, decreased appetite, lethargy and abnormal behaviour) have been reported in paediatric patients: nasopharyngitis (15.7 %), vomiting (14.7 %), somnolence (14.0 %), dizziness (13.5 %), pyrexia (13.0 %), convulsion (7.8 %), decreased appetite (5.9 %), pharyngitis (4.7 %), lethargy (2.7 %) and abnormal behaviour (1.7 %). Laboratory abnormalities: Abnormalities in liver function tests have been observed in placebo-controlled trials with VIMPAT® in adult patients with partial-onset seizures who were taking 1-3 concomitant antiepileptic medicinal products. Elevations of ALT to $\geq 3 \times \text{ULN}$ occurred in 0.7% (7/935) of VIMPAT® patients and 0% (0/356) of placebo patients. Multiorgan Hypersensitivity Reactions: Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, DRESS) have been reported in patients treated with some antiepileptic medicinal products. These reactions are variable in expression but typically present with fever and rash and can be associated with involvement of different organ systems. If multiorgan hypersensitivity reaction is suspected, VIMPAT® should be discontinued.

Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information.

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Forward looking statements – UCB

This press release contains forward-looking statements including, without limitation, statements containing the words “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “continue” and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or 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 or within expected timing, 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, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, 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. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal

models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that

implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only 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 or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

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