UCB showcases new research and continued epilepsy leadership at the 2017 American Epilepsy Society Annual Meeting

- UCB reinforces commitment to delivering improved patient value by presenting latest epilepsy research findings
- 25 scientific presentations illustrate and reinforce UCB's dedication to improving patient value in epilepsy
- Congress also provides platform for collaboration, ideation and exploration of how best to 'Rise Above Expectations' for people with epilepsy

Brussels (Belgium), 1 December 2017 – 07:00 (CET): UCB is pleased to announce that 25 scientific abstracts have been accepted for poster presentation at the upcoming 71st American Epilepsy Society (AES) Annual Meeting, which takes place from 1-5 December in Washington, D.C., USA.[1-25]

Posters being presented further describe VIMPAT® (lacosamide) CV and BRIVIACT® (brivaracetam) CV clinical data,[1-11] including results from a recently concluded placebo-controlled trial which studied VIMPAT® as adjunctive therapy in children aged four years and older and adolescents with uncontrolled focal (partial-onset) seizures,[4] and updated data on the safety and tolerability of long-term treatment with adjunctive BRIVIACT® for focal seizures.[9]

UCB will also present preliminary data on two UCB developmental drug candidates for epilepsy, padsevonil and radiprodil.[12-19]

Additional presentations will share a wide range of data, including results from a social media survey to assess perceptions of patient information leaflets, and pre-clinical data identifying a potential target receptor for epilepsy therapy.[20-25]

Alongside scientific presentations, UCB will be facilitating conversations with delegates throughout the meeting, focusing on rising above expectations of care for people with epilepsy. Harnessing innovative technologies, such as virtual reality seizure simulation, UCB is encouraging

collaborations which may address the challenges faced by people living with epilepsy, and sharing real-world examples of positive programs and partnerships such as the UCB Family Epilepsy Scholarship Program™ and Canine Assistants™ partnership. At AES, UCB will further demonstrate and reinforce its neurology passion, expertise and commitment to the goal of addressing and improving the lived experiences of people with epilepsy.

"*At UCB, we strive to develop solutions that help patients achieve their treatment goals, and to support the wider epilepsy community in elevating the overall patient experience. We are excited to showcase the scale and passion of our commitment at AES"* said Jeff Wren, Head of UCB's Neurology Patient Value Unit. "*We have a longstanding heritage in epilepsy and take pride in the breadth and depth of our research we share each year at AES. This year is no exception, and we're very excited to contribute our expertise to help support patients live their lives at their ideal."*

In the U.S., VIMPAT® is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of VIMPAT® injection in pediatric patients has not been established, VIMPAT® injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and older).[26]

In the EU, 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.[27]

In the U.S., BRIVIACT® is indicated for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.[28]

In the EU, BRIVIACT® is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.[29]

Additional label and important safety information about VIMPAT® and BRIVIACT® can be found below.[26-29]

The following is a guide to the 25 UCB-sponsored poster presentations at the 71st AES Annual Meeting, held from 1-5 December in Washington, D.C., USA.

VIMPAT® (lacosamide) CV Posters

1. **[1.281] Efficacy and tolerability of adjunctive lacosamide in children and adolescents with uncontrolled focal seizures: a randomized, double-blind, placebo-controlled trial**
   Farkas V. et al.
   Saturday, 2 December, 2017, Poster Session 1

2. **[1.282] Long-term tolerability of adjunctive lacosamide in pediatric patients aged 4 to <16 years with focal seizures: an interim pooled analysis of data from open-label trials**
   Yuen N. et al.
   Saturday, 2 December, 2017, Poster Session 1

3. **[1.284] Lipid levels during lacosamide and controlled-release carbamazepine monotherapy: post-hoc analysis of a prospective randomized double-blind trial**
   Dimova S. et al.
   Saturday, 2 December, 2017, Poster Session 1

4. **[1.285] Tolerability of lacosamide and controlled-released carbamazepine monotherapy by number of additional medical conditions: post-hoc analysis of a prospective randomized double-blind trial in adults with newly-diagnosed epilepsy**
   Ryan S. et al.
   Saturday, 2 December, 2017, Poster Session 1

5. **[1.292] Long-term safety of lacosamide monotherapy in adults with partial-onset seizures: interim results of a phase 3 study**
   Yamamoto T. et al.
   Saturday, 2 December, 2017, Poster Session 1

BRIVIACT® (brivaracetam) CV Posters

6. **[1.317] Characteristics of patients with epilepsy newly initiated on brivaracetam: a retrospective claims database analysis**
   Fishman J. et al.
   Saturday, 2 December, Poster Session 1

7. **[2.286] Safety and tolerability of long-term brivaracetam monotherapy in patients with focal seizures**
   Fakhoury T. et al.
   Sunday, 3 December, 2017, Poster Session 2

8. **[2.287] Long-term follow-up study of patients with epilepsy who switched from adjunctive levetiracetam to brivaracetam**
   Borghs S. et al.
   Sunday, 3 December, 2017, Poster Session 2

9. **[2.288] Update on safety and tolerability of long-term treatment with adjunctive brivaracetam for focal seizures**
   King-Stephens D. et al.
   Sunday, 3 December, 2017, Poster Session 2

10. **[2.289] Pediatric safety and tolerability data from two open-label studies of adjunctive brivaracetam in infants and children with epilepsy**
    Badalamenti V. et al.
    Sunday, 3 December, 2017, Poster Session 2

11. **[2.300] Temporal occurrence of CNS treatment-emergent adverse events: evidence from brivaracetam clinical trials**
    Meador KJ. et al.
    Sunday, 3 December, 2017, Poster Session 2

Presentations on UCB's Investigational Pipeline

12. **[1.270] Functional characterization of padsevonil on GABA-A receptors**
    Wolff C. et al.
    Saturday, 2 December, 2017, Poster Session 1

13. **[1.271] Padsevonil binds to synaptic vesicle protein 2 A, B, and C isoforms and to the benzodiazepine site on the GABA-A receptor**
    Wood M. et al.
    Saturday, 2 December, 2017, Poster Session 1

14. **[1.272] Protective effects of padsevonil in acute seizure models**
    Leclercq K. et al.
    Saturday, 2 December, 2017, Poster Session 1

15. **[1.273] Protective effects of the antiepileptic drug candidate padsevonil in rat/mouse amygdala kindling models**
    Kaminski RM. et al.
    Saturday, 2 December, 2017, Poster Session 1

16. **[1.283] Efficacy and tolerability of adjunctive padsevonil in adults with drug-resistant focal onset seizures: a randomized, double-blind, placebo-controlled, proof-of-concept trial**
    Muglia P. et al.
    Saturday, 2 December, 2017, Poster Session 1

17. **[1.286] SV2A and GABA-A receptor occupancy in healthy volunteers after single and multiple doses of padsevonil using the PET ligands UCB-J and flumazenil**
    Sciberras D. et al.
    Saturday, 2 December, 2017, Poster Session 1

18. **[1.287] Padsevonil single and multiple rising dose safety, tolerability, pharmacokinetics, and pharmacodynamics in healthy volunteers**
    Otoul C. et al.
    Saturday, 2 December, 2017, Poster Session 1

19. **[1.312] *GRIN2B* gain of function mutations are sensitive to inhibition by radiprodil, a selective GluN2B negative allosteric modulator**
    Mullier B. et al.
    Saturday, 2 December, 2017, Poster Session 1

Epilepsy Posters

20. **[1.002] CSF-1R antagonists reduce epileptic activity and pro-inflammatory cytokine release in the organotypic hippocampal slice model of post-traumatic epileptogenesis**
    Niespodziany I. et al.
    Saturday, 1 December, 2017, Poster Session 1

21. **[1.299] Antiepileptic drug treatment patterns in women of child bearing age with epilepsy: a US database analysis**
Thurman D. et al.
Saturday, 2 December, 2017, Poster Session 1

22. **[1.411] Meeting the needs of clinicians, people with epilepsy, and caregivers in underserved areas: the epilepsy foundation connectors project methodology**
Osborne Shafer P. et al.
Saturday, 2 December, 2017, Poster Session 1

23. **[1.412] Increasing quality of care measures and self-management behaviors: a case study from the EPILEPSY FOUNDATION CONNECTORS PROJECT in Michigan**
Kakacek JRM. et al.
Saturday, 2 December, 2017, Poster Session 1

24. **[2.002] A systems-level framework for drug discovery identifies CSF-1R as a novel anti-epileptic drug target**
Johnson MR. et al.
Sunday, 2 December, 2017, Poster Session 2

25. **[3.294] Social media survey of EPILEPSY ADVOCATE followers to assess perceptions and utilization of patient information leaflets (PILs) and acceptance and recognition of pictograms**
Thompson J. et al.
Monday, 4 December, 2017, Poster Session 3

The UCB Outcomes Accelerator & Catalyst Café will also be open throughout the AES congress and is located within the main exhibition hall from December 2 – 4, Booth 603 & Pavilion F.

Additionally two scientific exhibits, featuring a selection of UCB sponsored posters, will be hosted during AES 2017:

- ***UCB Epilepsy Heritage*, Sunday, December 3, 2-5 PM, Room 101**
- ***UCB Commitment to Science*, Monday, December 4, 8-11 AM, Salon A**

About Epilepsy [30,31]

Epilepsy is a disease of the brain affecting approximately 65 million people worldwide. It is defined as either the occurrence of two or more unprovoked seizures >24 hours apart or one unprovoked (or reflex) seizure and a probability of further seizures occurring over the next 10 years that is similar to the general recurrence risk (at least 60%) after two unprovoked seizures or 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.

About UCB in Epilepsy
UCB has a longstanding commitment to improving the lives of people with epilepsy around the world. With over 20 years of experience in the research and development of antiepileptic drugs, our goal is to become a preferred partner for the global epilepsy community, improving knowledge about and access to effective solutions to help patients better manage their individual epilepsy journeys. We strive to 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 people with epilepsy.

About VIMPAT® [26,27]
In the U.S., VIMPAT® is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of VIMPAT® injection in pediatric patients has not been established, VIMPAT® injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and older). VIMPAT® was approved in the U.S. in 2008 as an add-on therapy for adult patients. VIMPAT® was approved as monotherapy for adults in August 2014. VIMPAT® is available in three formulations: oral tablets, oral solution, and intravenous (IV) injection. Important safety information about VIMPAT® in the U.S. is available below.

VIMPAT® (lacosamide) was first launched in the European Union in September 2008, as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy. In September 2017 the use of VIMPAT® was expanded to adolescents and children from 4 years of age. In countries of the EU, VIMPAT® is available as film-coated tablets, syrup and solution for infusion. VIMPAT® solution for infusion is an alternative for patients when oral administration is temporarily not feasible. The availability of the oral tablets, oral syrup, and intravenous (IV) injection allows for consistent patient treatment. In Asia, VIMPAT® is available in Korea, Hong Kong, Malaysia, Philippines and Thailand, and was approved for use in Japan in 2016, where the product will be jointly commercialised by Daiichi Sankyo. VIMPAT® is not approved in China. Important safety information about VIMPAT® is available below.

Important Safety Information about VIMPAT® in the U.S.[26]

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 clinical trials, 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. Dizziness and ataxia were also observed in pediatric clinical trials.

Cardiac Rhythm and Conduction Abnormalities:
PR interval prolongation
Dose-dependent prolongations in PR interval with VIMPAT have been observed in clinical studies in adult patients and in healthy volunteers. Second-degree and complete AV block have been reported in patients with seizures. When VIMPAT is given with other drugs that prolong the PR interval, further PR prolongation is possible. Use VIMPAT with caution in patients with known cardiac conduction problems (e.g., marked first-degree AV block, second-degree or higher AV block and sick sinus syndrome without pacemaker), sodium channelopathies (e.g., Brugada Syndrome), or with severe cardiac disease such as myocardial ischemia or heart failure, or structural heart disease. Also, use VIMPAT with caution in patients on concomitant medications that prolong PR interval (e.g., beta-blockers and calcium channel blockers) because of a risk of AV block or bradycardia. In such patients, obtaining an ECG before beginning VIMPAT, and after VIMPAT is titrated to steady-state maintenance dose, is recommended. In addition, closely monitor these patients if they are administered VIMPAT through the intravenous route.
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 multiorgan hypersensitivity, has been reported with antiepileptic drugs. 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 symptom 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
Adjunctive therapy: In the adult placebo-controlled clinical trials, 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.
Monotherapy: In the adult clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo-controlled trials, with the exception of insomnia (occurred at a higher rate of ≥2%).
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, 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.

Dosing Considerations
VIMPAT injection is for intravenous and adult use only when oral administration is temporarily not feasible. The loading dose for adult patients should be administered with medical supervision

considering the VIMPAT pharmacokinetics and increased incidence of CNS adverse reactions. The safety of VIMPAT injection and the use of a loading dose in pediatric patients have not been studied.
Dosage adjustments are recommended for patients with mild or moderate hepatic impairment or severe renal impairment. Use in patients with severe hepatic impairment is not recommended. Perform dose titration with caution in all patients with renal and/or hepatic impairment.

VIMPAT is a Schedule V controlled substance.

Please refer to full Prescribing Information provided by the sales representative, and visit www.VIMPATHCP.com.

For more information on VIMPAT® contact 844-599-CARE (2273).

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

Important Safety Information about VIMPAT® in the EU and EEA[27]
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 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. A maximum dose of 300 mg/day is recommended for paediatric patients weighing 50 kg or more and for adult patients with mild to moderate hepatic impairment. 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 ≤ 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 ≤ 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. Cases with second- and third-degree AV block associated with VIMPAT® treatment have been reported in post-marketing experience. VIMPAT® should be used with caution in patients with known conduction problems, severe cardiac disease (e.g. history of myocardial infarction or heart failure), in elderly patients, or when VIMPAT® is used in combination with products known to be associated with PR prolongation. 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. Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheaded 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 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). It contains 3.7 g sorbitol (E420) per dose (200 mg lacosamide), corresponding to a calorific value of 9.7 kcal. Patients with rare hereditary problems of fructose intolerance should not take this medicine. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. VIMPAT® syrup and the solution for infusion contain sodium, which should be taken into consideration for patients on a controlled sodium diet. 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 (≥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 (≥1% - <10%) are depression, confusional state, insomnia, balance disorder, coordination abnormal, 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 open-label studies in adjunctive therapy in children from 4 years to less than 16 years was

consistent with the safety profile observed in adults. In the paediatric population the most frequently reported adverse reactions were vomiting (17.1 %), dizziness (16.7 %), somnolence (12.1 %), headache (11.7 %) and convulsion (10.1 %). Additional adverse reactions reported in children were decreased appetite (6.6 %), lethargy (4.3 %) and abnormal behaviour (1.9 %). Laboratory abnormalities: Abnormalities in liver function tests have been observed in controlled trials with VIMPAT® in adult patients with partial-onset seizures who were taking 1-3 concomitant antiepileptic medicinal products. Elevations of ALT to ≥3XULN 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. Date of revision: 14th September 2017 http://www.ema.europa.eu/.

About BRIVIACT® [28,29]

BRIVIACT® (brivaracetam) is a new molecular entity that was rationally designed and developed by UCB.

In the U.S., BRIVIACT® is approved for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.[28]

In the EU, BRIVIACT® is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.[29]

BRIVIACT® was approved in the EU and the U.S. in 2016 as an add-on therapy for adult patients.

BRIVIACT® is available in three formulations (film-coated tablets, oral solution, and injection).

Important Safety Information about BRIVIACT® in the U.S.[28]

WARNINGS AND PRECAUTIONS

Suicidal Behavior and Ideation: Antiepileptic drugs, including BRIVIACT®, increase the risk of suicidal behavior and ideation. Monitor patients taking BRIVIACT® for the emergence or worsening of depression; unusual changes in mood or behavior; or suicidal thoughts, behavior, or self-harm. Advise patients, their caregivers, and/or families to be alert for these behavioral changes and report them immediately to a healthcare provider.

Neurological Adverse Reactions: BRIVIACT® causes somnolence, fatigue, dizziness, and disturbance in coordination. Somnolence and fatigue-related adverse reactions were reported in 25% of patients taking at least 50 mg per day of BRIVIACT® compared to 14% of patients taking placebo. Dizziness and disturbance in gait and coordination were reported in 16% of patients taking at least 50 mg per day of BRIVIACT® compared to 10% of patients taking placebo. The risk

is greatest early in treatment but can occur at any time. Monitor patients for these signs and symptoms and advise them not to drive or operate machinery until they have gained sufficient experience on BRIVIACT®.

Psychiatric Adverse Reactions: BRIVIACT® causes psychiatric adverse reactions, including non-psychotic and psychotic symptoms. These events were reported in approximately 13% of patients taking at least 50 mg per day of BRIVIACT® compared to 8% of patients taking placebo. A total of 1.7% of adult patients taking BRIVIACT® discontinued treatment due to psychiatric reactions compared to 1.3% of patients taking placebo. Advise patients to report these symptoms immediately to a healthcare provider.

Hypersensitivity: BRIVIACT® can cause hypersensitivity reactions. Bronchospasm and angioedema have been reported. Discontinue BRIVIACT® if a patient develops a hypersensitivity reaction after treatment. BRIVIACT® is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.

Withdrawal of Antiepileptic Drugs: As with all antiepileptic drugs, BRIVIACT® should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

Dosing Considerations

Dose adjustments are recommended for patients with all stages of hepatic impairment.

When BRIVIACT® is co-administered with rifampin, an increase in the BRIVIACT® dose is recommended.

Adverse Reactions

The most common adverse reactions (at least 5% for BRIVIACT® and at least 2% more frequently than placebo) are somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms.

BRIVIACT® is a Schedule V controlled substance.

Please refer to full Prescribing Information at http://www.briviact.com/briviact-PI.pdf.

For more information on BRIVIACT®, contact 844-599-CARE (2273).

BRIVIACT® is a registered trademark of the UCB Group of Companies.

Important Safety Information about BRIVIACT® in the EU and EEA[29]

BRIVIACT® (brivaracetam) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. Contraindications Hypersensitivity to the active substance, other pyrrolidone derivatives or any of the excipients. Special warnings and precautions for use Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic drugs (AEDs) in several indications, including BRIVIACT®. Patients should be monitored for signs of suicidal ideation and behaviour and appropriate treatment should be considered. Patients (and caregivers) should be advised to seek medical advice should any signs of suicidal ideation or behaviour emerge. Dose

adjustments are recommended for patients with hepatic impairment (50 mg/day starting dose should be considered, up to maximum daily dose of 150 mg administered in 2 divided doses). BRIVIACT® film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take BRIVIACT®. Both the solution for injection/infusion and the oral solution contain sodium – to be taken into consideration for patients on a controlled sodium diet. The oral solution contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine. The oral solution contains methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed). Interaction with other medicinal products and other forms of interaction With co-administration of BRIVIACT® 200 mg single dose and ethanol 0.6 g/L continuous infusion in healthy subjects there was no pharmacokinetic interaction, but the effect of alcohol on psychomotor function, attention and memory was doubled. Intake of BRIVIACT® with alcohol is not recommended. In healthy subjects, co-administration with rifampicin, a strong enzyme-inducer (600 mg/day for 5 days), decreased BRIVIACT® area under the plasma concentration curve (AUC) by 45%. Prescribers should consider adjusting the dose of BRIVIACT® for patients starting or ending treatment with rifampicin. Other strong enzyme-inducers (such as St John´s wort [Hypericum perforatum]) may also decrease the systemic exposure of BRIVIACT®. Therefore, starting or ending treatment with St John's wort should be done with caution. In vitro interaction studies have shown that BRIVIACT® can inhibit CYP2C19, therefore BRIVIACT® may increase plasma concentrations of medicinal products metabolised by CYP2C19 (e.g., lanzoprazole, omeprazole, diazepam). CYP2B6 induction has not been investigated in vivo and BRIVIACT® may decrease plasma concentrations of medicinal products metabolised by CYP2B6 (e.g. efavirenz). In vitro studies have also shown that BRIVIACT® has inhibitory effects on OAT3. BRIVIACT® 200 mg/day may increase plasma concentrations of medicinal products transported by OAT3. BRIVIACT® plasma concentrations are decreased when co-administered with strong enzyme inducing antiepileptic drugs (carbamazepine, phenobarbital, phenytoin) but no dose adjustment is required. Effects on ability to drive and use machines BRIVIACT®, has minor or moderate influence on the ability to drive and use machines. Patients should be advised not to drive a car or to operate other potentially hazardous machines until they are familiar with the effects of BRIVIACT®, on their ability to perform such activities. Undesirable effects The most frequently reported adverse reactions with BRIVIACT® (reported by >10% of patients) were somnolence (14.3%) and dizziness (11.0%). They were usually mild to moderate in intensity. Somnolence and fatigue (8.2 %) were reported at higher incidences with increasing dose. Other common adverse reactions (≥1% to <10%) were influenza, decreased appetite, depression, anxiety, insomnia, irritability, convulsion, vertigo, upper respiratory tract infections, cough, nausea, vomiting and constipation. Neutropenia has been reported in 0.5% (6/1,099) BRIVIACT®-patients and 0% (0/459) placebo-treated patients. Four of these patients had decreased neutrophil counts at baseline, and experienced additional decrease in neutrophil counts after initiation of BRIVIACT®. None of the six cases were severe, required any specific treatment, led to BRIVIACT® discontinuation or had associated infections. Suicidal ideation was reported in 0.3 % (3/1099) of BRIVIACT®-treated patients and 0.7 % (3/459) of placebo-treated patients. In short-term clinical studies of BRIVIACT® in patients with epilepsy, there were no cases of completed suicide and suicide attempt, however both were reported in the long-term open-label extension studies. In patients who were followed up in the open-label extension studies for up to 8 years, the safety profile was similar to that observed in the short-term, placebo-controlled studies. Overdose There is limited clinical experience with BRIVIACT® overdose in humans. Somnolence and dizziness were reported in a healthy subject taking a single dose of 1,400 mg of BRIVIACT®. There is no specific antidote. Treatment of an overdose should include general supportive measures. Since less than 10% of BRIVIACT® is excreted in urine, haemodialysis is not expected to significantly enhance BRIVIACT® clearance.

Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: April 2017. http://www.ema.europa.eu/

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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.

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USP-MP1117-0031