
UCB News

# UCB showcases new research at the 73rd American Academy of Neurology Annual Meeting to demonstrate broad neurology leadership and future portfolio

- UCB reinforces commitment to delivering increased patient value by presenting latest research findings in epilepsy, myasthenia gravis and Parkinson's disease
- Nine scientific presentations illustrate UCB's dedication to neurology and highlight the importance of gathering patient insight to transform patient experience
- UCB will also host a virtual symposium to discuss the clinical features of rare autoimmune neuromuscular diseases such as generalized myasthenia gravis, held on Tuesday 20 April, 09:00 – 10:00 EST

**Brussels (Belgium), 16 April 20 – 07:00 (CET):** UCB is pleased to announce that new data representing three neurological areas will be presented at the 73rd American Academy of Neurology (AAN) Annual Meeting, from 17-22 April 2021.[1-9] Spanning across epilepsy and Parkinson's disease, posters being presented at this year's virtual meeting will highlight the latest scientific and clinical developments, as well as a patient-led analysis to demonstrate the experience of living with myasthenia gravis (MG).

During this year's virtual AAN annual meeting, UCB will build on its heritage in epilepsy by presenting the latest data to further describe the safety and tolerability of long-term treatment with BRIVIACT® (brivaracetam) CV for focal seizures.[1-4,10,11] Two abstracts will also highlight data from the open-label ARTEMIS-2 trial for NAYZILAM® (midazolam) nasal spray CIV, for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity, (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.[5,6,12] This will be supplemented by a systemic review of real-world studies designed to better understand the behavioral adverse events which accompany common anti-seizure medications, and a population study which examined the underlying cause and extent of treatment delays for individuals with epilepsy. These studies further demonstrate UCB's commitment to create patient value by utilizing its investigational resources.

"*At UCB, we are driven by science to translate patient insights into unique, disease-modifying solutions that provide value and transform the patient experience. Optimizing patient experiences with our company and our medicines is integral to everything we do."* said Charl Van Zyl, Executive Vice President Neurology & Head of Europe/International Markets at UCB. "*We are excited to*

*showcase the scale and passion of our commitment at AAN. We are building on our legacy and expertise in epilepsy and Parkinson's disease by expanding our leadership and capabilities in new areas, and further cultivating our patient-centric culture."*

UCB is also focused on understanding the perspective of patients living with rare diseases, such as MG, and how it impacts day-to-day life. To this end, UCB convened an international patient council (PC) comprising nine individuals living with MG who serve as local/national patient advocates in seven countries (Europe and US). This patient-led analysis provides important insights into the reality of living with MG and will enable healthcare professionals to improve their understanding and management of their patients living with MG.[8]

*"Despite thousands of people across the world living with the unpredictable and, in many cases, debilitating impact of MG, there is still relatively little research describing true lived experiences faced by the MG patient community, from their perspective"* explained Nancy Law, former CEO and current Board Chair for the Myasthenia Gravis Foundation of America, and co-author of the abstract. She continued *"Most of the current data are about others' perception of patient lived experience. It is heartening that in accepting this data for presentation at their meeting, the American Academy of Neurology has recognized the importance of healthcare professionals truly understanding the perspectives of patients on their experiences. Patient collaborations, such as this one with the pharmaceutical industry, have potential to raise the patient voice and build better understanding about this rare neuro-muscular disease."*

Alongside scientific presentations, UCB will be facilitating a virtual symposium to discuss the clinical features of rare autoimmune neuromuscular diseases, such as MG, back to their origins in the immune system and gain a unique perspective on the lived patient experience. The symposium, which will be hosted virtually on Tuesday 20 April, 09:00-10:00 EST, has an esteemed faculty of James F. Howard, Jr., The University of North Carolina at Chapel Hill, Saiju Jacob, University Hospitals Birmingham, UK and Nancy Law, Myasthenia Gravis Foundation of America.

Finally, UCB will also present the latest findings in its research pipeline, by highlighting the early safety and tolerability data for its investigational molecule in Parkinson's disease, UCB0599.[9]

At AAN, 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 myasthenia gravis, epilepsy and Parkinson's disease.

**The following is a guide to the nine UCB-sponsored poster presentations at the 73rd American Academy of Neurology (AAN) Annual Meeting, held virtually 17-22 April.**

***BRIVIACT® (brivaracetam) CV abstracts***

1. **A systematic review of behavioral adverse events with brivaracetam, levetiracetam, perampanel, and topiramate in real-world studies**
   Steinhoff BJ, Klein P and Klitgaard H. et al.
   - Poster: P8.080

2. **Intravenous Antiseizure Medication Utilization Patterns Among Seizure Patients Treated in US Hospitals: a Database Analysis**
   Beaty S, Rosenthal N and Gayle J. et al.
   - Poster: P7.134

3. **Outcomes of Intravenous Use of Brivaracetam and Levetiracetam for the Treatment of Seizures in US Hospitals**
   Beaty S, Rosenthal N and Gayle J. et al.
   - Poster: P7.135

4. **Safety and Tolerability of Intravenous Brivaracetam in Patients with Epilepsy on Concomitant Levetiracetam Treatment**
   Martin MS, Elmoufti S and Dongre P et al.
   - Poster: P7.110

***NAYZILAM® (midazolam) CV abstracts***

5. **Treatment Satisfaction, Anxiety Level, and Confidence About Traveling With Midazolam Nasal Spray in Patients With Seizure Clusters: Phase III, Open-Label Extension Trial**
   Fakhoury T, Chen L and Bass A. et al.
   - Poster: P7.128

6. **Return to Full Baseline Functionality After Repeated Intermittent Use of Midazolam Nasal Spray in Patients With Seizure Clusters: Post-Hoc Analysis of an Open-Label Extension Trial**
   Detyniecki K, Brunnert M and Campos R. et al.
   - Poster: P7.131

***Epilepsy treatment delay abstract***

7. **The Role of Social Determinants in Epilepsy Treatment Delays for Arizonans on Medicaid**
   Sirven J, Sprout G and Speer M et al.
   - Poster: P11.008

***Myasthenia Gravis abstract***

8. **The Lived Experience of Myasthenia Gravis: A Patient-led Analysis**
   Law N, Davio K, and Blunk M et al.
   - Poster: P2.064

***Parkinson's disease abstract***

9. **Results from a Phase 1b Study of UCB0599, an Orally Available, Brain-penetrant Inhibitor of Alpha-synuclein (ASYN) Misfolding in People Living with Parkinson's Disease (PD)**
   Genius J, Dastros-Pitei D, and Detalle, L et al.

- Poster: P14.137

**About Epilepsy**
Epilepsy is a common neurological condition worldwide and affects approximately 50 million people.[13] Epilepsy and seizures can develop in any person at any age,[14] and is usually diagnosed after a person has had at least two seizures (or after one seizure with a high risk for more) that were not caused by some known medical condition.[15]

**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.

**About Seizure Clusters**
Seizure clusters are broadly defined as acute episodes of consecutive seizures that occur within a short period of time with a patient regaining consciousness during the interictal period. These clusters are also distinguishable from a person's typical seizure pattern.[16,17,18,19,20] Other names for seizure clusters include acute-repetitive seizures (ARS), serial seizures, crescendo seizures, and seizure flurries, which highlight the repetitive nature of the seizures.[21] Seizure clustering can increase the chance of emergency room visits.[16]

**About Generalized Myasthenia Gravis (gMG)**
Myasthenia gravis (MG) is a chronic, autoimmune, neuromuscular[22] condition where the body's immune system mistakenly targets the connection between the nerves and the muscles.[23] In people living with MG, voluntary muscles don't respond well to the signals sent by the brain.[24] People with MG may experience weakness of the eye muscles (called ocular myasthenia), drooping of one or both eyelids (ptosis), blurred or double vision (diplopia), a change in facial expression, difficulty swallowing, shortness of breath, impaired speech (dysarthria) and weakness in the arms, hands, fingers legs and neck.[22] The hallmark of myasthenia gravis is muscle weakness that worsens after periods of activity and improves after periods of rest.[22]

**About Parkinson's Disease**
Parkinson's Disease (PD) is a chronic, degenerative neurological disease which affects approximately 10 million people worldwide.[25] PD usually affects people over the age of 60.[25] PD develops with the loss of nerve cells in the brain that produce a chemical called dopamine. The symptoms of PD can have an impact on many dimensions of patients' lives. As dopamine levels fall, movement (motor) symptoms—tremors (uncontrollable shaking), rigidity (stiffness or muscle tensing) and bradykinesia (slowness and loss of spontaneous movement)—can progress, along with the underlying symptoms of PD, which are less well recognized and may be under-treated. Underlying symptoms can occur in over 90% of PD patients and include sleep disturbance, such as insomnia, vivid dreams and daytime drowsiness, mood and cognitive changes, pain,

depression, anxiety, apathy, gastrointestinal disorders, sexual dysfunction, bladder problems and fatigue.[25,26]

**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 operating in more than 40 countries, the company generated revenue of € 5.3 billion in 2020. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

**About BRIVIACT® [10, 11]**

BRIVIACT® (brivaracetam) CV was approved in the U.S. in 2016 as an add-on therapy for adult patients with partial onset seizures. BRIVIACT was approved as monotherapy for adults in September 2017, and as monotherapy or adjunctive therapy in patients four years of age and older with partial-onset seizures in 2018.

In the EU, BRIVIACT® is indicated as 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

BRIVIACT® is available in three formulations: oral tablets, oral solution, and solution for injection/infusion.

**Important Safety Information about BRIVIACT® in the EU and EEA[10]**

BRIVIACT® (brivaracetam) is indicated as 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. **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. BRIVIACT® film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take BRIVIACT®. Brivaracetam film-coated tablets, solution for injection/infusion and oral solution contain less than 1 mmol sodium (23mg) per tablet/vial/ml respectively, that is to say essentially 'sodium free'. The oral solution contains 239.8 mg sorbitol (E420) in each ml. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product. The oral solution contains methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed). Brivaracetam oral solution contains propylene glycol (E1520). **Posology** No dose adjustment is needed in adults with impaired renal function. Based on data in adults, no dose adjustment is necessary neither in paediatric patients with impaired renal function. In adults with hepatic impairment, a 50 mg/day starting dose should be considered. In children and adolescents weighing 50 kg or greater, a 50 mg/day starting dose is recommended. A maximum daily dose of 150 mg administered in 2 divided doses is recommended for all stages of hepatic impairment. In children and adolescents weighing

less than 50 kg, a 1 mg/kg/day starting dose is recommended. The maximum dose should not exceed 3 mg/kg/day. No clinical data are available in paediatric patients with hepatic impairment. **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. Limited clinical data are available implying that coadministration of cannabidiol may increase the plasma exposure of brivaracetam, possibly through CYP2C19 inhibition, but the clinical relevance is uncertain. 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 studies have shown that brivaracetam exhibits little or no inhibition of CYP450 isoforms except for CYP2C19. Brivaracetam 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. Very common adverse reactions (≥1% to <10%) were influenza, decreased appetite, depression, anxiety, insomnia, irritability, convulsion, vertigo, upper respiratory tract infections, cough, nausea, vomiting, constipation and fatigue. 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. Reactions suggestive of immediate (Type I) hypersensitivity have been reported in a small number of BRIVIACT® patients (9/3022) during clinical development. The safety profile of brivaracetam observed in children was consistent with the safety profile observed in adults. In the open label, uncontrolled, long-term studies suicidal ideation was reported in 4.7 % of paediatric patients (more common in adolescents) compared with 2.4 % of adults and behavioural disorders were reported in 24.8 % of paediatric patients compared with 15.1 % of adults. The majority of events were mild or moderate in intensity, were non-serious, and did not lead to

discontinuation of study drug. An additional adverse reaction reported in children was psychomotor hyperactivity (4.7 %). There are limited safety data from open-label studies in children from 1 month to <4 years of age. Limited data are available on neurodevelopment in children <4 years of age. No clinical data are available in neonates. **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: 25 November 2020.

http://www.ema.europa.eu/

**BRIVIACT® Indication and Select Important Safety Information in the U.S.**[11]

BRIVIACT® (brivaracetam) CV is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of BRIVIACT injection in pediatric patients has not been established, BRIVIACT injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older).

BRIVIACT® is associated with important warnings and precautions including suicidal behavior and ideation, somnolence, fatigue, dizziness, disturbance in gait and coordination, psychiatric adverse reactions including nonpsychotic and psychotic symptoms, and hypersensitivity reactions (bronchospasm and angioedema). BRIVIACT® is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.

In adult adjunctive therapy placebo-controlled clinical trials, the most common adverse reactions (at least 5% for BRIVIACT® and at least 2% more frequently than placebo) were somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms. Adverse reactions reported in clinical studies of pediatric patients 4 years to less than 16 years of age were generally similar to those in adult patients.

BRIVIACT® is a Schedule V controlled substance.

Please refer to full Prescribing Information at
https://www.ucb.com/_up/ucb_com_products/documents/Briviact_current_COL_03_2021.pdf.

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

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

**About NAYZILAM® (midazolam) nasal spray CIV in the U.S.**[12]
NAYZILAM is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are

distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

**Important Safety Information about NAYZILAM® in the U.S.[12]**

**CONTRAINDICATIONS**

NAYZILAM is contraindicated in patients with acute narrow-angle glaucoma.

**RISKS FROM CONCOMITANT USE WITH OPIOIDS**

**Concomitant use of benzodiazepines, including NAYZILAM, and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.**

**ABUSE, MISUSE, AND ADDICTION**

**The use of benzodiazepines, including NAYZILAM, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing NAYZILAM and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.**

**DEPENDENCE AND WITHDRAWAL REACTIONS AFTER USE OF NAYZILAM MORE FREQUENTLY THAN RECOMMENDED**

**The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although NAYZILAM is indicated only for intermittent use, if used more frequently than recommended abrupt discontinuation or rapid dosage reduction of NAYZILAM may precipitate acute withdrawal reactions, which can be life-threatening. For patients using NAYZILAM more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue NAYZILAM.**

**Risks of Cardiorespiratory Adverse Reactions**

Serious cardiorespiratory adverse reactions have occurred after administration of midazolam. Warn patients and caregivers about the risks of respiratory depression, cardiac and respiratory arrest. Respiratory depression was observed with the administration of NAYZILAM during clinical trials. Cardiac or respiratory arrest caused by NAYZILAM was not reported during clinical trials.

**Central Nervous System Depression from Concomitant Use with Other Central Nervous System Depressants, or Moderate or Strong CYP3A4 Inhibitors**

Drug products containing midazolam, including NAYZILAM, have a central nervous system (CNS) depressant effect.

Risks from Concomitant Use with Other CNS Depressants

NAYZILAM may cause an increased CNS-depressant effect when used with alcohol or other CNS depressants (e.g., opioids). Warn patients and caregivers that the use of NAYZILAM in combination with alcohol or other CNS depressant drugs may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect.

Risks from Concomitant Use with Moderate or Strong CYP3A4 Inhibitors

Concomitant use of NAYZILAM with moderate or strong CYP3A4 enzyme inhibitors may result in prolonged sedation because of a decrease in plasma clearance of midazolam. Caution patients against engaging in hazardous occupations requiring mental alertness, such as operating machinery, driving a motor vehicle or riding a bicycle until they have completely returned to their level of baseline functioning.

**Suicidal Behavior and Ideation**

Antiepileptic drugs (AEDs), including NAYZILAM, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Monitor patients treated with NAYZILAM 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.

**Impaired Cognitive Function**

Midazolam, including NAYZILAM, is associated with a high incidence of partial or complete impairment of recall for several hours following an administered dose. Counsel patients on when they can engage in activities requiring complete mental alertness, operate hazardous machinery, or drive a motor vehicle after taking NAYZILAM.

**Glaucoma**

Benzodiazepines, including NAYZILAM, can increase intraocular pressure in patients with glaucoma. NAYZILAM may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. NAYZILAM is contraindicated in patients with narrow-angle glaucoma.

**ADVERSE REACTIONS**

In the randomized, double-blind, placebo-controlled trial, the most common adverse reactions (≥5% in any NAYZILAM treatment group) were somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea.

**NAYZILAM is a Schedule IV controlled substance.**

Please refer to the full Prescribing Information at https://www.ucb-usa.com/nayzilam-prescribing-information.pdf

For additional medical information about NAYZILAM, patient assistance, or any other information please visit our website or call ucbCARES at 1-844-599-2273.

## About UCB0599

UCB0599 is an orally administered, brain penetrant, small molecule inhibitor of ASYN misfolding under investigation for the potential to slow the progression of PD.[28,29] UCB0599 was discovered by NeuroPore and was licenced to UCB in 2014 for further development.[28]

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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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**References**

**1.** Steinhoff BJ, Klein P and Klitgaard H. et al. A systematic review of behavioral adverse events with brivaracetam, levetiracetam, perampanel, and topiramate in real-world studies. 73rd annual meeting of American Academy of Neurology (AAN), April 17-22, 2021; Virtual, abstract P8.080

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**10.** European Medicines Agency. BRIVIACT® (brivaracetam) Summary of Product Characteristics (SmpC). Available at: https://www.ema.europa.eu/en/documents/product-information/briviact-epar-product-information_en.pdf (Last accessed: 13 April 2021).
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