UCB News

UCB showcases commitment to transforming outcomes for people living with epilepsy and rare epileptic syndromes at European Pediatric Neurology Society (EPNS) Annual Congress

- Data presented from UCB's wide ranging portfolio include the safety profile, efficacy, and tolerability of BRIVIACT® (brivaracetam) for the treatment of epileptic seizures in pediatric populations, and a review of published studies of the effectiveness of Fintepla®▼(fenfluramine) in reducing the frequency of generalized tonic-clonic (GTC) seizures in patients with rare epilepsy syndromes
- Survey data presented from a collaboration with European Collaboration for Epilepsy Trials (ECET) Consortium highlight unmet therapeutic needs of individuals living with Lennox-Gastaut syndrome in the European Union
- UCB will host a symposium entitled 'Dravet syndrome and Lennox-Gastaut syndrome: what's next in practice?', on Thursday 22nd June 13.00-14.00 (CEST)

Brussels, Belgium, 20 June 2023 – 07.00 AM CET – UCB will share the latest data from its epilepsy and rare epilepsy syndrome portfolio at the European Pediatric Neurology Society Annual Congress, June 20-24, 2023. The company will present seven abstracts, including one podium presentation, at the congress, across Dravet syndrome, Lennox-Gastaut syndrome (LGS), and focal (partial) epileptic seizures.

Mike Davis, Head of Global Epilepsy & Rare Syndromes, UCB, said: "At UCB, we aim to positively impact individuals, carers, and families living with epilepsies, through differentiated solutions, and we look forward to discussing our latest patient-centred data at EPNS. We continue to pioneer new research to better understand the fundamental mechanisms of the underlying different forms of epilepsy to foster discovery and development of potential disease modifying or even curative therapies, and the theme of the congress this year – 'From genome and connectome to cure' – aligns perfectly with our ambitions."

In LGS, the presentation of questionnaire survey data from a collaboration between Zogenix (now part of UCB) and the European Collaboration for Epilepsy Trials (ECET) Consortium, assessing the unmet medical needs of patients[1] will be complemented by interim results from a European real-world study of patients with LGS.[2] Between these two presentations, unmet needs and associated disease burden in LGS will be examined from both patient and clinical perspectives. The ECET survey illustrates the difficulty in managing LGS patients, finding that 69% (n=61 centres) of centres trialled five to ten anti-seizure medications and 18% of centres trialled more than ten such medications in their search for an effective regimen for each patient.[1]

In Dravet syndrome, post-hoc pooled responder data from two identical phase 3 trials of fenfluramine have been analysed in order to estimate the number-needed-to-treat (NNT) to reach clinically meaningful response thresholds[3]. With no head-to-head comparative trials in therapies approved for Dravet syndrome, these results may be used to guide clinical treatment decisions.[3] Data presented on fenfluramine also include a review of published studies of its effectiveness in reducing the frequency of generalized tonic-

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clonic (GTC) seizures in patients with rare epilepsy syndromes.[4] GTC seizures are a primary risk factor of sudden unexpected death in epilepsy (SUDEP).[5]

In focal epileptic seizures, data from EXPERIENCE - a pooled analysis of retrospective cohorts - will be presented, evaluating the safety profile, tolerability, and efficacy of brivaracetam in pediatric patients in routine clinical practice[6]. In addition, data on long-term (mean exposure 3.2 patient years) safety profile, tolerability, and efficacy, as well as the cognitive and behavioural impact of the treatment, will be shared.[7,8]

Ana Infante, Head of Epilepsy and European Operations said: "Our commitment to epilepsy research has never been stronger, and the presentations at EPNS speak to the depth of our data, and the variety of perspectives, clinical and patient, which we seek. Deeper insights on unmet needs within our therapy areas, such as those of people living with Dravet syndrome and Lennox-Gastaut syndrome, help us to target future research, and set our sights on addressing the issues in developmental and epileptic encephalopathies which impact the lives of patients every day."

Industry-sponsored symposium discussing developmental epileptic encephalopathies (DEEs)
'Dravet syndrome and Lennox-Gastaut syndrome: what's next in practice?', on Thursday 22nd June 13.00-14.00 (CEST) will elevate knowledge and awareness of the impact of DEEs, and the application of the latest clinical data to clinical practice through real-world case study discussion.

UCB presentations during EPNS 2023

Lead Author	Abstract title	Presentation Details (Timings CET)
Cross H	Effect of Fenfluramine on Generalized Tonic-Clonic Seizures in Rare Epilepsy Syndromes: A Review of Published Studies	Podium Presentation S: PA03 June 21, 2023 10:30 - 12:15 AM P: PA03-2633
Tchaicha S	Assessment of the Unmet Medical Needs of Patients With Lennox-Gastaut Syndrome: A Survey in Collaboration With the European Collaboration for Epilepsy Trials Consortium	ePoster S: PO04 June 21, 2023, 07:30 AM - 20:00 PM P: 2636
Besson H	12-Month Effectiveness and Tolerability of Brivaracetam in Pediatric Patients in the Real-World: Subgroup Data from the EXPERIENCE Analysis	Poster Presentation S: PO04 June 21, 2023 08:13 – 09:13 AM P: PO04-2117
Elshoff JP	Cognitive and Behavioral Effects of Adjunctive Brivaracetam in Children and Adolescents with Focal Seizures: Final Data From an Open-Label Follow-Up Trial	Poster Presentation S: PO04 June 21, 2023 07:43 – 08:43 AM P: PO04-2118
Klotz KA	Long-Term Safety and Efficacy of Adjunctive Brivaracetam in Pediatric Patients with Epilepsy: An Open-label, Follow-up Trial	Poster Presentation S: PO04 June 21, 2023

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		08:02 – 09:02 AM P: PO04-2119
Strzelczyk A	Interim results from a European real-world study in patients with Lennox-Gastaut Syndrome	ePoster S: PO03 June 21, 2023 07:30 AM - 20:00 PM P: 2109
Wheless JW	Fenfluramine Responder Analysis and Numbers Needed to Treat: Post-Hoc Pooled Analysis of Two Phase 3 Studies in Dravet Syndrome	Poster Presentation S: MP06 June 22, 2023 12:20 - 12:55 AM P: MP06-2635

About BRIVIACT® (brivaracetam) in the EU[9]

Important Safety Information about BRIVIACT in the EU

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 2 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 168 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. No clinical data are available in paediatric patients with renal impairment. In patients with hepatic impairment, the following adjusted doses, administered in 2 divided doses, approximately 12 hours apart, are recommended for all stages of hepatic impairment: In adults, adolescents and children weighing ≥50 kg, a 50 mg/day starting dose is recommended, with a maximum daily dose of 150 mg/day. For adolescents and children weighing from 20 kg to <50 kg, a 1 mg/kg/day starting dose is recommended, with a maximum daily dose of 3 mg/kg/day. For children weighing from 10 kg to <20 kg, a 1 mg/kg/day starting dose is recommended, with a maximum daily dose of 4 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., lansoprazole, 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 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 from 1 month of age 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 assessed from 6 years onwards (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 %). No specific pattern of adverse event (AE) was identified in children from 1 month to < 4 years of age when compared to older paediatric age groups. No significant safety information was identified indicating the increasing incidence of a particular AE in this age group. As data available in children younger than 2 years of age are limited, brivaracetam is not indicated in this age range. 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. The following adverse reactions were reported with brivaracetam overdose: nausea, vertigo, balance disorder, anxiety, fatigue, irritability, aggression, insomnia, depression, and suicidal ideation in the post-marketing experience. In general, the adverse reactions associated with brivaracetam overdose were consistent with the known adverse reactions. 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.
https://www.ema.europa.eu/en/documents/product-information/briviact-epar-product-information_en.pdf

About FINTEPLA®▼(fenfluramine) oral solution in EU[10]

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. Fenfluramine is a serotonin releasing agent, and thereby stimulates multiple 5-HT receptor sub-types through the release of serotonin. Fenfluramine may reduce seizures by acting as an agonist at specific serotonin receptors in the brain, including the 5-HT1D, 5-HT2A, and 5-HT2C receptors, and also by acting on the sigma-1 receptor. The precise mode of action of fenfluramine in Dravet syndrome and Lennox-Gastaut syndrome is not known.

Fenfluramine oral solution is available under a controlled access program to ensure regular cardiac monitoring and to mitigate potential off-label use.

Please refer to Fintepla, INN-Fenfluramine (europa.eu) (SmPC) before prescribing.

▼*This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

Important Safety Information about FINTEPLA®▼ in EU

Aortic or mitral valvular heart disease and pulmonary arterial hypertension

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Because of reported cases of valvular heart disease that may have been caused by fenfluramine at higher doses used to treat adult obesity, cardiac monitoring must be performed using echocardiography. In the controlled clinical studies of fenfluramine for the treatment of Dravet syndrome and Lennox-Gastaut syndrome, no valvular heart disease was observed. Prior to starting treatment, patients must undergo an echocardiogram to establish a baseline prior to initiating treatment and exclude any pre-existing valvular heart disease or pulmonary hypertension. Echocardiogram monitoring should be conducted every 6 months for the first 2 years and annually thereafter. If an echocardiogram indicates pathological valvular changes, a follow-up echocardiogram should be considered at an earlier timeframe to evaluate whether the abnormality is persistent. If pathological abnormalities on the echocardiogram are observed, it is recommended to evaluate the benefit versus risk of continuing fenfluramine treatment with the prescriber, caregiver, and cardiologist. If treatment is stopped because of aortic or mitral valvular heart disease, appropriate monitoring and follow-up should be provided in accordance with local guidelines for the treatment of aortic or mitral valvular heart disease. With past use in higher doses to treat adult obesity, fenfluramine was reported to be associated with pulmonary arterial hypertension. Pulmonary arterial hypertension was not observed in the clinical programme, but because of the low incidence of this disease, the clinical trial experience with fenfluramine is inadequate to determine if fenfluramine increases the risk for pulmonary arterial hypertension in patients with Dravet syndrome and Lennox-Gastaut syndrome. If echocardiogram findings are suggestive of pulmonary arterial hypertension, a repeat echocardiogram should be performed as soon as possible and within 3 months to confirm these findings. If the echocardiogram finding is confirmed suggestive of an increased probability of pulmonary arterial hypertension defined as "intermediate probability" by the 2015 European Society of Cardiology (ESC) and the European Respiratory Society (ERS) Guidelines, it should lead to a benefit-risk evaluation of continuation of Fintepla by the prescriber, carer, and cardiologist. If the echocardiogram finding, after confirmation, suggests of a high probability of pulmonary arterial hypertension, as defined by the 2015 ESC and ERS Guidelines, it is recommended fenfluramine treatment should be stopped.

Decreased appetite and weight loss
Fenfluramine can cause decreased appetite and weight loss. An additive effect on decreased appetite can occur when fenfluramine is combined with other anti-epileptic medicines, for example stiripentol. The decrease in weight appears to be dose related. Most subjects resumed weight gain over time while continuing treatment. The patient's weight should be monitored. A benefit risk evaluation should be undertaken prior to commencing treatment with fenfluramine in patients with a history of anorexia nervosa or bulimia nervosa.

Fintepla controlled access programme
A controlled access programme has been created to 1) prevent off-label use in weight management in obese patients and 2) confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking Fintepla.

Somnolence
Fenfluramine can cause somnolence. Other central nervous system depressants, including alcohol, could potentiate the somnolence effect of fenfluramine.

Suicidal behaviour and ideation
Suicidal behaviour and ideation have been reported in patients treated with anti-epileptic medicines in several indications. A meta-analysis of randomised placebo-controlled trials with anti-epileptic medicines that did not include fenfluramine has shown a small increased risk of suicidal behaviour and ideation. The mechanism of this risk is not known, and the available data do not exclude the possibility of an increased risk for fenfluramine. Patients and caregivers of patients should be advised to seek medical advice should any signs of suicidal behaviour and ideation emerge.

Serotonin syndrome
As with other serotonergic agents, serotonin syndrome, a potentially life-threatening condition, may occur with fenfluramine treatment, particularly with concomitant use of other serotonergic agents (including SSRIs, SNRIs, tricyclic antidepressants, or triptans); with agents that impair metabolism of serotonin such as MAOIs; or with antipsychotics that may affect the serotonergic neurotransmitter systems. Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (eg, hyperreflexia, incoordination), and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhoea). If concomitant treatment with fenfluramine and other serotonergic agents that may affect the serotonergic systems is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.

Increased seizure frequency
As with other anti-epileptic medicines, a clinically relevant increase in seizure frequency may occur during treatment with fenfluramine, which may require adjustment in the dose of fenfluramine and/or concomitant anti-epileptic medicines, or discontinuation of fenfluramine, should the benefit-risk be negative.

Cyproheptadine

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Cyproheptadine is a potent serotonin receptor antagonist and may therefore decrease the efficacy of fenfluramine. If cyproheptadine is added to treatment with fenfluramine, patients should be monitored for worsening of seizures. If fenfluramine treatment is initiated in a patient taking cyproheptadine, fenfluramine's efficacy may be reduced.

Glaucoma
Fenfluramine can cause mydriasis and can precipitate angle closure glaucoma. Discontinue therapy in patients with acute decreases in visual acuity. Consider discontinuation if there is ocular pain and another cause cannot be determined.

Effect of CYP1A2 and CYP2B6 inducers
Co-administration with strong CYP1A2 inducers or CYP2B6 inducers will decrease fenfluramine plasma concentrations, which may lower the efficacy of fenfluramine. If co-administration of a strong CYP1A2 or CYP2B6 inducer with fenfluramine is considered necessary, the patient should be monitored for reduced efficacy and a dose increase of fenfluramine could be considered provided that it does not exceed twice the maximum daily dose (52 mg/day). If a strong CYP1A2 or CYP2B6 inducer is discontinued during maintenance treatment with fenfluramine, consider gradual reduction of the fenfluramine dosage to the dose administered prior to initiating the inducer.

Effect of CYP1A2 or CYP2D6 inhibitors
Initiation of concomitant treatment with a strong CYP1A2 or CYP2D6 inhibitor may result in higher exposure and, therefore, adverse events should be monitored, and a dose reduction may be needed in some patients.

Coadministration of a single 0.35 mg/kg dose of fenfluramine with fluvoxamine (a strong CYP1A2 inhibitor) at steady state (50 mg once daily) in healthy volunteers increased the AUC0-t of fenfluramine by a ratio of 2.1-fold and the Cmax by a ratio of 1.2-fold, and decreased the AUC0-t of norfenfluramine by a ratio of 1.3-fold and the Cmax by a ratio of 1.4-fold, as compared to fenfluramine administered alone.

Coadministration of a single 0.35 mg/kg dose of fenfluramine with paroxetine (a strong CYP2D6 inhibitor) at steady state (30 mg once daily) in healthy volunteers increased the AUC0-t of fenfluramine by a ratio of 1.8-fold and the Cmax by a ratio of 1.1-fold, and decreased the AUC0-t of norfenfluramine by a ratio of 1.2-fold and the Cmax by a ratio of 1.3-fold, as compared to fenfluramine administered alone.

Excipients
This medicinal product contains sodium ethyl para-hydroxybenzoate (E 215) and sodium methyl para hydroxybenzoate (E 219) which may cause allergic reactions (possibly delayed). It also contains sulfur dioxide (E 220) which may rarely cause severe hypersensitivity reactions and bronchospasm. Patients with rare glucose-galactose malabsorption should not take this medicinal product. This medicinal product contains less than 1 mmol sodium (23 mg) per the maximum daily dose of 12 mL, that is to say essentially 'sodium-free'. This medicinal product contains glucose which may be harmful to the teeth.

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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 approximately 8,600 people in approximately 40 countries, the company generated revenue of €5.5 billion in 2022. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements
This press release may contain 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: the global spread and impact of COVID-19, 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, will progress to product approval 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 differences 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's 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 it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB 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. Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

References:

1. Tchaicha S, Arzimanoglou A, Holmes E, et al. Assessment of the Unmet Medical Needs of Patients With Lennox-Gastaut Syndrome: A Survey in Collaboration With the European Collaboration for Epilepsy Trials Consortium. Abstract 2636 presented at European Paediatric Neurology Society (EPNS), Prague, Czech Republic, 20-24 June 2023.

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2. Strzelczyk A, Gil-Nagel A, Striano P, et al. Lennox-Gastaut Syndrome characteristics: Interim results from a European real-world point-in-time study. Abstract 2109 presented at European Paediatric Neurology Society (EPNS), Prague, Czech Republic, 20-24 June 2023.
3. Wheless JW, Dai D, Gammaitoni AR, et al. Fenfluramine Responder Analysis and Numbers Needed to Treat: Post-Hoc Pooled Analysis of Two Phase 3 Studies in Dravet Syndrome. Abstract MP06-2635 presented at European Paediatric Neurology Society (EPNS), Prague, Czech Republic, 20-24 June 2023.
4. Cross H, Devinsky O, Gil-Nagel A. Effect of Fenfluramine on Generalized Tonic-Clonic Seizures in Rare Epilepsy Syndromes: A Review of Published Studies. Abstract PA03-2633 presented at European Paediatric Neurology Society (EPNS), Prague, Czech Republic, 20-24 June 2023.
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7. Klotz A, Lagae L, Fogarasi A, et al. Long-term Safety and Efficacy of Adjunctive Brivaracetam in Pediatric Patients with Epilepsy: An Open-label, Follow-up Trial. Abstract P: PO04-2119 presented at European Paediatric Neurology Society (EPNS), Prague, Czech Republic, 20-24 June 2023.
8. Elshoff JP, Fleyshman S, De La Loge C, et al. Cognitive and Behavioral Effects of Adjunctive Brivaracetam in Children and Adolescents with Focal Seizures: Final Data From an Open-label Follow-up Trial. P: PO04-2118 presented at European Paediatric Neurology Society (EPNS), Prague, Czech Republic, 20-24 June 2023.
9. Briviact® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/briviact-epar-product-information_en.pdf Accessed on May 2023.
10. Fintepla® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf. Accessed on May 2023.

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