UCB News

UCB presents new data highlighting developments across expansive neurology portfolio at 76th American Academy of Neurology (AAN) Annual Meeting

- **Diverse and patient-focused data set comprises 17 abstracts including one oral presentation**
- **Features new data analyses for UCB's generalized myasthenia gravis (gMG) treatments, including post hoc and open-label extension results from the pivotal Phase 3 MycarinG study and additional Interim Analyses of RAISE-XT for the approved treatments RYSTIGGO®▼ (rozanolixizumab) and ZILBRYSQ®▼ (zilucoplan)**
- **Data on BRIVIACT® (brivaracetam), FINTEPLA®▼ (fenfluramine), and STACCATO® alprazolam showcase commitment to patients and momentum of UCB's epilepsy and rare syndromes portfolio**

Brussels (Belgium), 12 April 2024: 07:00 (CET) UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today announced the latest research from its expansive neurology portfolio and pipeline to be presented at the 76th American Academy of Neurology (AAN) Annual Meeting, April 13-18, 2024, in Denver, Colorado, USA.

A total of 17 abstracts, including an oral presentation, will feature data from studies of four approved and one investigational medicine and technologies for generalized myasthenia gravis (gMG), epilepsies including Dravet syndrome and focal (partial) epileptic seizures.

Key UCB scientific and patient-focused data to be presented at AAN include:

gMG

- Post hoc and open-label extension analyses from the pivotal Phase 3 MycarinG study for rozanolixizumab, including impact of treatment on physical fatigue and muscle fatigability in adult patients with gMG
- An oral presentation on long-term safety and efficacy of zilucoplan in gMG in an interim analysis of RAISE-XT
- An interim analysis of a Phase 3b study on efficacy, and patient preference for subcutaneous zilucoplan in Myasthenia Gravis after switching from intravenous complement component 5 inhibitors
- Results from a discrete choice study looking at patient preferences in gMG treatment attributes

Epilepsy and rare epilepsy syndromes

- Focal-onset seizures (FOS) - interim results of 12-month real-world study (BRITOBA) evaluating adjunctive brivaracetam in earlier treatment lines in adults
- Epilepsy - subgroup data from the international EXPERIENCE analysis assessing brivaracetam in epilepsy patients with cognitive or learning disability or psychiatric comorbidities

- Prolonged seizures - three Phase 1 studies evaluating the safety, tolerability, and pharmacokinetics of single-use inhaled alprazolam (an investigational treatment for potential termination of prolonged epileptic seizures) in different populations
- Dravet syndrome - a retrospective analysis using US claims data of healthcare utilization and persistence in patients with Dravet syndrome
- Epilepsy disease management - expert consensus recommendations from the Seizure Termination Project*, highlighting best practice for rapid and early seizure termination and timing for intervention

"The new analyses from the Phase 3 MycarinG and Phase 3 RAISE XT open-label extension (OLE) studies being presented at this year's AAN meeting reinforce the potential of our recently approved gMG treatments, RYSTIGGO® ▼ and ZILBRYSQ® ▼, to offer targeted treatments for adult gMG patients, tailored to their individual needs and preferences," commented Donatello Crocetta, Head of Global Rare Disease & Rare Medical, UCB. *"These data further underscore UCB's innovative approach to evolving science into meaningful treatment solutions that help improve long term patient outcomes of people living with this rare neuromuscular disease, and more widely as part of the integrated neurology portfolio's commitment to patient-focused solutions."*

"For people living with epilepsy and rare epilepsy syndromes, the data being presented at this year's AAN meeting showcase how we are transforming experiences and outcomes and redefining the future of epilepsy care," said Mike Davis, Global Head of Epilepsy & Rare Syndromes, UCB. *"Everything we do is centered around helping people and families living with seizure disorders achieve their ideal and maximize their life opportunities."*

UCB presentations during AAN 2024

Lead author	Abstract title	Presentation Details (Timings MDT)
gMG		
A Habib	Clinically Meaningful Improvement in Physical Fatigue and Muscle Weakness Fatigability with Rozanolixizumab: Post-Hoc Analysis of MG Symptoms PRO Responder Rate in the MycarinG study	Poster Presentaiton P001 April 15, 2024 11:45 AM - 12:45 PM MDT
J Zhou	Characteristics, Treatment Patterns and Disease Burden of Juvenile Myasthenia Gravis in the United States **Disclaimer:** Rystiggo and Zilbrysq are not indicated for the use in juvenile myasthenia gravis (JMG) by any regulatory authority worldwide	Poster Presentation P017 April 15, 2024 11:45 AM - 12:45 PM MDT
O Qureshi	Interactions of Fcγ receptors with an IgG4 format, anti-FcRn monoclonal antibody, rozanolixizumab	Poster Presentation P002 April 15, 2024 11:45 AM - 12:45 PM MDT
C Mansfield	Patient Preferences for Myasthenia Gravis Treatments: A Discrete-Choice Experiment	Poster Presentation P013 April 15, 2024 11:45 AM - 12:45 PM MDT

V Bril	The Safety and Efficacy of Chronic Weekly Rozanolixizumab Treatment in Patients with gMG (MG0004)	Poster Presentation P017 April 15, 2024 11:45 AM - 12:45 PM MDT
JF Howard	Long-Term Safety and Efficacy of Zilucoplan in Myasthenia Gravis: Additional Interim Analyses of RAISE-XT	Oral Presentation P002 April 15, 2024 1:12 PM MDT
Z Mahuwala	Drivers of New Rozanolixizumab Treatment Cycles in Patients with Generalized Myasthenia Gravis in the Phase 3 MycarinG and Open-Label Extension Studies	Poster Presentation P003 April 17,2024 11:45 AM - 12:45 PM MDT
R Pascuzzi	Response to Rozanolixizumab Across Treatment Cycles in Patients with Generalized Myasthenia Gravis: A Post-hoc Analysis	Poster Presentation P005 April 17, 2024 11:45 AM - 12:45 PM MDT
M Freimer	Efficacy and Patient Preference for Subcutaneous Zilucoplan in Myasthenia Gravis After Switching from Intravenous Complement Component 5 Inhibitors: An Interim Analysis of a Phase 3b Study	Poster Presentation P006 April 17, 2024 11:45 AM - 12:45 PM MDT
Epilepsy & Rare Epilepsy Syndromes		
V Villanueva	12-Month Effectiveness and Tolerability of Brivaracetam in Patients With Epilepsy and Cognitive or Psychiatric Comorbidities: Subgroup Data From the International EXPERIENCE Pooled Analysis	Poster Presentation P009 April 16, 2024 5:30 – 6:30 PM MDT
S Knake	Brivaracetam Adjunctive Therapy in Earlier Treatment Lines in Adults With Focal-onset Seizures in Europe and Canada: Interim Results of 12-month Real-world Data From BRITOBA	Poster Presentation P008 April 16, 2024 5:30 – 6:30 PM MDT
P Perucca	Pregnancy Outcomes Following Exposure to Lacosamide: Prospective Data From Spontaneous and Solicited Reports	Poster Presentation P011 April 15, 2024 11:45 AM – 12:45 PM MDT
D Miller	**Pulmonary Safety of Staccato® Alprazolam in Healthy Participants and Participants with Mild Asthma: Phase 1, Randomized, Double-Blind, Placebo-Controlled Trial	Poster Presentation P009 April 17, 2024 8:00 – 9:00 AM MDT
P Klein	**Pharmacokinetics and Tolerability of Single-dose Staccato® Alprazolam in Adolescents with Epilepsy and Population PK Analysis to Support Dose Selection in Adolescents	Poster Presentation P002 April 17, 2024 8:00 – 9:00 AM MDT

R Roebling	**Pharmacokinetics of Staccato® Alprazolam in Healthy Adult Participants: Phase 1, Randomized, Placebo-Controlled Ethno-Bridging Study	Poster Presentation P007 April 17, 2024 8:00 – 9:00 AM MDT
JE Pina Garza	*Expert Consensus Recommendations on Seizure Emergencies Suitable for Rapid and Early Seizure Termination (REST) and Timing of Intervention	Poster Presentation P003 April 17, 2024 8:00 – 9:00 AM MDT
S Jaganathan	Healthcare Utilization and Persistence in Patients with Dravet Syndrome: A Retrospective Analysis Using US Claims Data	Poster Presentation P003 April 14, 2024 8:00 – 9:00 AM MDT

*The Seizure Termination Project was funded by UCB Pharma.

**STACCATO® alprazolam is an investigational treatment, and its safety and efficacy has not been established. It is not currently approved for use by any regulatory authority worldwide.

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Important Safety Information about RYSTIGGO®▼ (rozanolixizumab) in the EU[1]

▼ *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.*

Rystiggo is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.[1]

The most commonly reported adverse reactions were headache (48.4 %), diarrhea (25.0 %) and pyrexia (12.5 %). The adverse reactions from the placebo-controlled study in gMG are as follow: Very common (≥ 1/10) headache, diarrhea and pyrexia; Common (≥ 1/100 to < 1/10) rash, angioedema, arthralgia and injection site reactions. Headache was the most common reaction reported in 31 (48.4 %) and 13 (19.4 %) of the patients treated with rozanolixizumab and placebo, respectively. All headaches, except 1 (1.6 %) severe headache, were either mild (28.1 % [n=18]) or moderate (18.8 % [n=12]) and there was no increase in incidences of headache with repeated cyclic treatment.

Rozanolixizumab is contra-indicated in patients with hypersensitivity to the active substance or to any of the excipients.

Treatment with rozanolixizumab in patients with impending or manifest myasthenic crisis has not been studied. The sequence of therapy initiation between established therapies for MG crisis and rozanolixizumab, and their potential interactions, should be considered.
Aseptic meningitis (drug induced aseptic meningitis) has been reported following rozanolixizumab treatment at a higher dose with subsequent recovery without sequelae after discontinuation. If symptoms consistent with aseptic meningitis occur, diagnostic workup and treatment should be initiated as per standard of care.

Due to its mechanism of action, the use of rozanolixizumab may increase the patient's susceptibility to infections. Treatment with rozanolixizumab should not be initiated in patients with a clinically important active infection until the infection is resolved or is adequately treated. During treatment with rozanolixizumab, clinical signs and symptoms of infections should be monitored. If a clinically important active infection occurs, withholding rozanolixizumab until the infection has resolved should be considered.

Hypersensitivity reactions including mild to moderate rash or angioedema were observed in patients treated with rozanolixizumab. Patients should be monitored during treatment with rozanolixizumab and for 15 minutes after the administration is complete for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, rozanolixizumab infusion should be discontinued and appropriate measures should be initiated if needed. Once resolved, administration may be resumed

Immunization with vaccines during rozanolixizumab therapy has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with vaccines are unknown. All vaccines should be administered according to immunization guidelines and at least 4 weeks before initiation of treatment. For patients that are on treatment, vaccination with live or live attenuated vaccines is not recommended. For all other vaccines, they should take place at least 2 weeks after the last infusion of a treatment cycle and 4 weeks before initiating the next cycle.

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/rystiggo-epar-product-information_en.pdf.

GL-BR-2400001 Date of preparation: April 2024

Important Safety Information about ZILBRYSQ®▼ (zilucoplan) in the EU[2]

▼ *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*.

Zilbrysq is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.[2]

The most frequently reported adverse reactions were injection site reactions (injection site bruising (13.9%) and injection site pain (7.0%) and upper respiratory tract infections (nasopharyngitis (5.2%), upper respiratory tract infection (3.5%) and sinusitis (3.5%). The adverse reactions from the pooled placebo controlled (n=115) and open-label extension (n=213) studies in gMG are as follows: Very common adverse reactions: (≥ 1/10): Upper respiratory tract infections and Injection site reactions; Common adverse reactions (≥ 1/100 to < 1/10) Diarrhea, Lipase increased, Amylase increased and Morphea; Uncommon adverse reaction (≥ 1/1000 to < 1/100) blood eosinophils increased. Zilucoplan is contra-indicated in patients with hypersensitivity to the active substance or to any of the excipients, in patients who are not currently vaccinated against *Neisseria meningitidis* and in patients with unresolved *Neisseria meningitidis* infection. Due to its mechanism of action, the use of zilucoplan may increase the patient's susceptibility to infections with *Neisseria meningitidis*. As a precautionary measure, all patients must be vaccinated against meningococcal infections, at least 2 weeks prior to the start of treatment. If treatment needs to start less than 2 weeks after vaccination against meningococcal infections, the patient must receive appropriate prophylactic antibiotic treatment until 2 weeks after the first vaccination dose. Meningococcal vaccines reduce but do not completely eliminate the risk of meningococcal infections. Vaccines against serogroups A, C, Y, W, and where available, serogroup B, are recommended for preventing the commonly pathogenic meningococcal serogroups. Vaccination and prophylactic antibiotic treatment should occur according to most current relevant guidelines. During treatment, patients should be monitored for signs and symptoms of meningococcal infection and evaluated immediately if infection is suspected. In case of a suspected meningococcal infection, appropriate measures such as treatment with antibiotics and discontinuation of treatment, should be taken until the meningococcal infection can be ruled out. Patients should be instructed to seek immediate medical advice if signs or symptoms of meningococcal infections occur. Prescribers should be familiar with the educational materials for the management of meningococcal infections and provide a patient alert card and patient/carer guide to patients treated with zilucoplan. In addition to Neisseria meningitidis, patients treated with zilucoplan may also be susceptible to infections with other Neisseria species, such as gonococcal infections. Patients should be informed on the importance of gonorrhea prevention and treatment. Prior to initiating zilucoplan therapy, it is recommended that patients initiate immunizations according to current immunization guidelines. *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/zilbrysq-epar-product-information_en.pdf. EC Date of approval 01 Dec 2023*.

Important Safety Information about FINTEPLA®▼ (fenfluramine) in the EU[3]

▼ *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.*

Indications: 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.

Dosage and Administration: Please refer to SmPC for full information. Should be initiated and supervised by physicians with experience in the treatment of epilepsy. Fintepla is prescribed and dispensed according to the Fintepla controlled access programme. *Dravet syndrome: Patients who are **not** taking stiripentol:* Starting dose is 0.1 mg/kg twice daily (0.2 mg/kg/day). After 7 days, if tolerated, can increase dose to 0.2 mg/kg twice daily (0.4 mg/kg/day). After an additional 7 days, if tolerated and further seizure reduction required, can increase dose to a maximum of 0.35 mg/kg twice daily (0.7 mg/kg/day), which is the recommended maintenance dose. Patients requiring more rapid titration may increase the dose every 4 days. Do not exceed maximum daily dose of 26 mg (13 mg twice daily). *Patients who are taking stiripentol*: Starting dose is 0.1 mg/kg twice daily (0.2 mg/kg/day). After 7 days, if tolerated, can increase dose to 0.2 mg/kg twice daily (0.4 mg/kg/day), which is the recommended maintenance dose. Patients requiring more rapid titration may increase the dose every 4 days. Do not exceed a total dose of 17 mg (8.6 mg twice daily). *Lennox-Gastaut syndrome:* Starting dose is 0.1 mg/kg twice daily (0.2 mg/kg/day). After 7 days, the dose should be increased to 0.2 mg/kg twice daily (0.4 mg/kg/day), if tolerated. After an additional 7 days, if tolerated, dose should be increased to 0.35 mg/kg twice daily (0.7 mg/kg/day), which is the recommended maintenance dose. Do not exceed maximum daily dose of 26 mg (13 mg twice daily). *Discontinuation*: When discontinuing treatment, decrease the dose gradually. As with all anti-epileptic medicines, avoid abrupt discontinuation when possible to minimize the risk of increased seizure frequency and status epilepticus. A final echocardiogram should be conducted 3-6 months after the last dose of treatment with fenfluramine. *Renal impairment:* Generally, no dose adjustment is recommended when administered to patients with mild to severe renal impairment, however, a slower titration may be considered. If adverse reactions are reported, a dose reduction may be needed. Has not been studied in patients with end-stage renal disease. Not known if fenfluramine or its active metabolite, norfenfluramine, is dialyzable. *Hepatic impairment:* Hepatic impairment: Generally, no dose adjustment is recommended when Fintepla is administered without concomitant stiripentol to patients with mild and moderate hepatic impairment (Child-Pugh Class A and B). In patients with severe hepatic impairment (Child-Pugh C) not receiving concomitant stiripentol, the maximum dosage is 0.2mg/kg twice daily, and the maximal total daily dose is 17 mg. There are limited clinical data on the use of Fintepla with stiripentol in patients with mild impaired hepatic function. A slower titration may be considered in patients with hepatic impairment and a dose reduction may be needed if adverse reactions are reported. No clinical data is available on the use of Fintepla with stiripentol in moderate and severe hepatic impairment, therefore not recommended for use. *Elderly*: No data available. *Pediatric population:* Safety and efficacy in children below 2 years of age not yet established. No data available. **Contraindications:** Hypersensitivity to active substance or any excipients. Aortic or mitral valvular heart disease and pulmonary arterial hypertension. Within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome. **Warnings and Precautions**: *Aortic or mitral valvular heart disease and pulmonary arterial hypertension:* Prior to starting treatment, patients must undergo an echocardiogram to establish a baseline and exclude any pre-existing valvular heart disease or pulmonary hypertension. Conduct echocardiogram monitoring every 6 months for the first 2 years and annually thereafter. If an echocardiogram indicates pathological valvular changes, consider follow-up earlier to evaluate whether the abnormality is persistent. If pathological abnormalities seen on echocardiogram, evaluate the benefit versus risk of continuing fenfluramine treatment with the prescriber, caregiver and cardiologist. Once treatment is discontinued for any reasons, a final echocardiogram should be conducted 3-6 months after the last dose of treatment with fenfluramine. If echocardiogram findings suggestive of pulmonary arterial hypertension, perform a repeat echocardiogram as soon as possible and within 3 months to confirm these findings. If echocardiogram finding is confirmed suggestive of an increased probability of pulmonary arterial hypertension defined as intermediate probability, conduct a benefit-risk evaluation of continuation of Fintepla by the prescriber, carer and cardiologist. If echocardiogram suggests a high probability, it is recommended fenfluramine treatment should be stopped. *Decreased appetite and weight loss:* Fenfluramine can cause decreased appetite and weight loss - an additive effect can occur in combination with other anti-epileptic medicines such as stiripentol. Monitor the patient's

weight. Undertake risk-benefit evaluation before starting treatment if 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 which could be potentiated by other central nervous system depressants. *Suicidal behaviour and ideation:* Suicidal behaviour and ideation have been reported in patients treated with anti-epileptic medicines in several indications. Advise patients and caregivers to seek medical advice should any signs of suicidal behaviour and ideation emerge. *Serotonin syndrome:* Serotonin syndrome, a potentially life-threatening condition, may occur with fenfluramine treatment, particularly with concomitant use of other serotonergic agents; with agents that impair metabolism of serotonin such as MAOIs; or with antipsychotics that may affect the serotonergic neurotransmitter systems. Carefully observe the patient, particularly during treatment initiation and dose increases. *Increased seizure frequency*: A clinically relevant increase in seizure frequency may occur during treatment, 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*: Cyproheptadine is a potent serotonin receptor antagonist and may therefore decrease the efficacy of fenfluramine. If cyproheptadine is added to treatment with fenfluramine, monitor patient 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 ocular pain of unknown origin. *Effect of CYP1A2 or 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 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. *Excipients*: Contains sodium ethyl para-hydroxybenzoate (E 215) and sodium methyl para-hydroxybenzoate (E 219) - 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 medicine. The product contains less than 1 mmol sodium (23 mg) per the maximum daily dose of 12 mL; essentially 'sodium-free'. Contains glucose - may be harmful to teeth. *Interactions:* Pharmacodynamic interactions with other CNS depressants increase the risk of aggravated central nervous system depression. An increase in dose may be necessary when coadministered with rifampicin or a strong CYP1A2 or CYP2B6 inducer. In in vitro studies co-administration with a strong CYP1A2 or CYP2D6 inhibitor may result in higher exposure (see section 4.4 of the SmPC). Co-administration with CYP2D6 substrates or MATE1 substrates may increase their plasma concentrations. Co-administration with CYP2B6 or CYP3A4 substrates may decrease their plasma concentrations. *Pregnancy and lactation*: Limited data in pregnant women. As a precaution, avoid use of Fintepla in pregnancy. It is unknown whether fenfluramine/metabolites are excreted in human milk. Animal data have shown excretion of fenfluramine/metabolites in milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Fintepla taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. *Drive and use machines.:* Fintepla has moderate influence on the ability to drive/ use machines as it may cause somnolence and fatigue. Advise patients not to drive or operate machinery until they have sufficient experience to gauge whether it adversely affects their abilities.

Adverse effects: *Dravet syndrome: Very common (≥1/10):* Upper respiratory tract infection, decreased appetite, somnolence, diarrhoea, pyrexia, fatigue, blood glucose decreased, echocardiogram abnormal

(Consisted of trace and mild mitral regurgitation, and trace aortic regurgitation, which are considered physiologic). *Common (≥1/100 to <1/10):* Bronchitis, abnormal behaviour, aggression, agitation, insomnia, mood swings, ataxia, hypotonia, lethargy, seizure, status epilepticus, tremor, constipation, salivary hypersecretion, weight decreased and blood prolactin increased. *Not known (cannot be estimated from the available data):* Pulmonary arterial hypertension. *Lennox-Gastaut syndrome: Very common (≥1/10):* Upper respiratory tract infection, decreased appetite, somnolence, diarrhoea, vomiting, fatigue. *Common (≥1/100 to <1/10):* Bronchitis, influenza, pneumonia, aggression, seizure, status epilepticus, lethargy, tremor, constipation, salivary hypersecretion, blood prolactin increased, weight decreased, fall. Refer to SmPC for other adverse reactions.

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/fintepla-epar-product-information_en.pdf

Important Safety Information about BRIVIACT® (brivaracetam) in the EU[4]

Therapeutic indications: BRIVIACT 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.

Posology and method of administration: The physician should prescribe the most appropriate formulation and strength according to weight and dose. It is recommended to parent and care giver to administer BRIVIACT oral solution with the measuring device (10 ml or 5 ml oral dosing syringe) provided in the carton box. BRIVIACT solution for injection/infusion is an alternative route of administration for patients when oral administration is temporarily not feasible. There is no experience with twice daily intravenous administration of brivaracetam for a period longer than 4 days. *Adults:* The recommended starting dose is 50 or 100 mg/day based on physician's assessment of required for seizure reduction versus potential side effects. Brivaracetam can be taken with or without food. Based on individual patient response and tolerability, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day. *Children and adolescents weighing 50 kg or more:* The recommended starting dose is 50 mg/day. Brivaracetam may also be initiated at 100 mg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 100 mg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day. *Children and adolescents weighing from 20 kg to less than 50 kg:* The recommended starting dose is 1 mg/kg/day. Brivaracetam may also be initiated at doses up to 2 mg/kg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 2 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day to 4 mg/kg/day. *Children weighing from 10 kg to less than 20 kg:* The recommended starting dose is 1 mg/kg/day. Brivaracetam may also be initiated at doses up to 2.5 mg/kg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 2.5 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day to 5 mg/kg/day. For adults, adolescents and children from 2 years of age, the dose should be administered in two equally divided doses, approximately 12 hours apart.

If patients miss one dose or more, it is recommended that they take a single dose as soon as they remember and take the following dose at the usual morning or evening time. Brivaracetam oral solution can be diluted in water or juice shortly before swallowing; a nasogastric tube or a gastrostomy tube may also be used. Brivaracetam may be initiated with either intravenous or oral administration. When converting from oral to intravenous administration or vice versa, the total daily dose and frequency of administration should be

maintained. Brivaracetam may be administered as an intravenous bolus without dilution or diluted in a compatible diluent and administered as a 15-minute intravenous infusion. This medicinal product must not be mixed with other medicinal products. Brivaracetam bolus injection or intravenous infusion has not been studied in acute conditions, e.g. status epilepticus, and is therefore not recommended for such conditions For patients from 16 years of age, if brivaracetam has to be discontinued, it is recommended that the dose is reduced gradually by 50 mg/day on a weekly basis. For patients below the age of 16 years, if brivaracetam has to be discontinued, it is recommended that the dose is reduced by a maximum of half the dose every week until a dose of 1 mg/kg/day (for patients with a body weight less than 50 kg) or 50 mg/day (for patients with body weight of 50 kg or more) is reached. After 1 week of treatment at 50 mg/day, a final week of treatment at 20 mg/day is recommended. No dose adjustment is needed for elderly patients (≥65 years of age) or for those with renal impairment. Based on data in adults, no dose adjustment is necessary in pediatric patients with impaired renal function. No clinical data are available on pediatric patients with renal impairment. Brivaracetam is not recommended for patients with end-stage renal disease undergoing dialysis due to lack of data. Exposure to brivaracetam was increased in patients with chronic liver disease. 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 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 is recommended, with a maximum daily dose of 4 mg/kg/day. No clinical data are available in pediatric patients with hepatic impairment. The efficacy of brivaracetam in pediatric patients aged less than 2 years has not yet been established.

Contraindications: Hypersensitivity to the active substance, other pyrrolidone derivatives or any of the excipients. **Special warnings and precautions for use:** Suicidal ideation and behavior have been reported in patients treated with anti-epileptic drugs (AEDs) in several indications, including brivaracetam. Patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers) should be advised to seek medical advice should any signs of suicidal ideation or behavior emerge. Clinical data on the use of brivaracetam in patients with pre-existing hepatic impairment are limited. Dose adjustments are recommended for patients with hepatic impairment. Brivaracetam film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take brivaracetam. 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'. Brivaracetam 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). **Interaction with other medicinal products and other forms of interaction:** In clinical studies, although patient numbers were limited, brivaracetam had no observed benefit over placebo among patients taking concomitant levetiracetam. No additional safety or tolerability concern was observed. In an interaction study between brivaracetam 200 mg single dose and ethanol 0.6 g/L continuous infusion in healthy volunteers, there was no pharmacokinetic interaction, but the effect of alcohol on psychomotor function, attention and memory was approximately doubled with the intake of brivaracetam. Intake of brivaracetam with alcohol is not recommended. In vitro data suggest that brivaracetam has a low interaction potential. The main disposition pathway of brivaracetam® is by CYP-independent hydrolysis; a second pathway involves hydroxylation mediated by CYP2C19. Brivaracetam plasma concentrations may increase when co-administered with CYP2C19 strong inhibitors (e.g. fluconazole, fluvoxamine), but the risk of a clinically relevant CYP2C19 mediated interaction is considered to be low. 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 the strong enzyme inducer rifampicin (600 mg/day for 5 days), decreased brivaracetam area under the plasma concentration curve (AUC) by 45%. Prescribers should consider adjusting the dose of brivaracetam in patients starting or ending treatment with rifampicin. Brivaracetam plasma concentrations are decreased when co-administered with strong enzyme-inducing AEDs (carbamazepine, phenobarbital, phenytoin) but no dose adjustment is required. Other strong enzyme inducers such as St John's wort (Hypericum perforatum) may decrease the systemic exposure of brivaracetam. Starting or ending treatment with St John's wort should be done with caution. Brivaracetam at 50 or 150 mg/day did not affect the AUC of midazolam (metabolised by CYP3A4). The risk of clinically relevant CYP3A4 interactions is considered low. In vitro studies have shown that brivaracetam exhibits little or no inhibition of CYP450 isoforms except for CYP2C19 and may therefore increase plasma concentrations of medicinal products metabolised by CYP2C19 (e.g. lansoprazole, omeprazole, diazepam). Brivaracetam did not induce CYP1A1/2 but induced CYP3A4 and CYP2B6 in vitro. No CYP3A4 induction was found in vivo. CYP2B6 induction has not been investigated in vivo and brivaracetam may decrease plasma concentrations of medicinal products metabolised by CYP2B6 (e.g. efavirenz). In vitro interaction studies to determine the potential inhibitory effects on transporters concluded that there were no clinically relevant effects, except for OAT3. In vitro, brivaracetam inhibits OAT3 with a half maximal inhibitory concentration 42-fold higher than the C_{max} at the highest clinical dose. Brivaracetam 200 mg/day may increase plasma concentrations of medicinal products transported by OAT3. Brivaracetam is a moderate reversible inhibitor of epoxide hydrolase, resulting in an increased concentration of carbamazepine epoxide, an active metabolite of carbamazepine. In controlled clinical studies, carbamazepine epoxide plasma concentration increased by a mean of 37%, 62% and 98% with little variability at Brivaracetam doses of 50 mg/day, 100 mg/day and 200 mg/day, respectively. No safety risks were observed. There was no additive effect of brivaracetam and valproate on the AUC of carbamazepine epoxide. No dose adjustment is needed when brivaracetam is co-administered with carbamazepine, phenobarbital or phenytoin. Brivaracetam had no clinically relevant effect on the plasma concentrations of clobazam, clonazepam, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate, valproic acid or zonisamide. There are no data available on the effects of clobazam, clonazepam, lacosamide, pregabalin or zonisamide on brivaracetam plasma concentrations. Co-administration of brivaracetam (100 mg/day) with an oral contraceptive containing ethinylestradiol (0.03 mg) and levonorgestrel (0.15 mg) did not influence the pharmacokinetics of either substance. However, when brivaracetam was co-administered at a dose of 400 mg/day (twice the recommended maximum daily dose), a reduction in estrogen and progestin AUCs of 27% and 23%, respectively, was observed without impact on suppression of ovulation. **Pregnancy:** Data on the use of brivaracetam in pregnant women are limited. There are no data on placental transfer in humans, but brivaracetam was shown to readily cross the placenta in rats. The potential risk for humans is unknown. Animal studies did not detect any teratogenic potential of brivaracetam. In clinical studies, adjunctive brivaracetam used concomitantly with carbamazepine induced a dose-related increase in the concentration of the active metabolite, carbamazepine-epoxide. There are insufficient data to determine the clinical significance of this effect in pregnancy. Brivaracetam should not be used during pregnancy unless clinically necessary. **Breast-feeding:** Brivaracetam is excreted in human breast milk. The decision to discontinue either breastfeeding or brivaracetam should be made based on the benefit of the medicinal product to the mother. In case of co-administration of brivaracetam and carbamazepine, the amount of carbamazepine-epoxide excreted in breast milk could increase. The clinical significance remains unknown. **Fertility:** No human data on the effect of brivaracetam on fertility are available. There was no effect on fertility in rats. **Effects on ability to drive and use machines**: Brivaracetam 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 brivaracetam on their ability to perform such activities. **Undesirable effects:** The most frequently reported adverse reactions with brivaracetam were somnolence

(14.3%) and dizziness (11.0%); they were usually mild-to-moderate in intensity. Somnolence and fatigue were reported at a higher incidence with increasing dose. Very common adverse reactions (≥1%-<10%) were influenza, decreased appetite, depression, anxiety, insomnia, irritability, convulsion, vertigo, upper respiratory tract infections, cough, nausea, vomiting, constipation and fatigue. Neutropenia was reported in 6/1099 (0.5%) of brivaracetam and none (0/459) of the placebo-treated patients. Four of these subjects had decreased neutrophil counts at baseline. None of the neutropenia cases were severe, required any specific treatment or led to discontinuation of brivaracetam and none had associated infections. Suicidal ideation was reported in 0.3% (3/1099) of brivaracetam and 0.7% (3/459) of placebo-treated patients. In short-term clinical studies of brivaracetam in patients with epilepsy, there were no cases of completed suicide and suicide attempt; however, both were reported in open-label extension studies. 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 pediatric patients (assessed from 6 years onwards, more common in adolescents) compared with 2.4 % of adults and behavioral disorders were reported in 24.8 % of pediatric 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 pediatric 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. Limited clinical data are available in neonates. Reactions suggestive of immediate (Type I) hypersensitivity have been reported in a small number of brivaracetam patients (9/3022) during clinical development. **Overdose:** There is limited clinical experience with brivaracetam overdose in humans. Somnolence and dizziness have been reported in a healthy subject taking a single dose of 1,400 mg of brivaracetam. 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 for overdose with brivaracetam. Treatment of an overdose should include general supportive measures. Since <10% of brivaracetam is excreted in urine, haemodialysis is not expected to significantly enhance brivaracetam 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

Important Safety Information about VIMPAT® (lacosamide) in the EU[5]

Therapeutic indications: VIMPAT® is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalization in adults, adolescents and children from 2 years of age with epilepsy. VIMPAT® is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adults, adolescents and children from 2 years of age with epilepsy and in the treatment of primary generalized tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalized epilepsy.

Posology and method of administration: Lacosamide therapy can be initiated with either oral administration (either tablets or syrup) or IV administration (solution for infusion). The physician should prescribe the most appropriate formulation and strength according to weight and dose. A loading dose may be initiated in patients in situations when the physician determines that rapid attainment of lacosamide steady

state plasma concentration and therapeutic effect is warranted. It should be administered under medical supervision with consideration of the potential for increased incidence of serious cardiac arrhythmia and Central Nervous System (CNS) adverse reactions. Administration of a loading dose has not been studied in acute conditions such as status epilepticus. Administration of a loading dose has not been studied in children. Use of a loading dose is not recommended in adolescents and children weighing less than 50 kg. No dose adjustment is necessary in mildly and moderately renally impaired adult and pediatric patients (CLCR > 30 ml/min). In pediatric 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 pediatric 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 pediatric 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. A maximum dose of 300 mg/day is recommended for pediatric patients weighing 50 kg or more and for adult patients with mild to moderate hepatic impairment. Based on data in adults, in pediatric 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 pediatric 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. Lacosamide is not recommended for use in children below the age of 4 years in the treatment of primary generalized tonic-clonic seizures and below the age of 2 years in the treatment of partial-onset seizures as there are limited data on safety and efficacy in these age groups. **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:** Suicidal ideation and behavior have been reported in patients treated with antiepileptic medicinal products in several indications. Therefore, patients should be monitored for signs of suicidal ideation and behavior and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge. Dose-related prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with underlying proarrhythmic conditions such as known cardiac conduction problems or severe cardiac diseases (e.g. myocardial ischemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products, as well as in elderly patients. In these patients it should be considered to perform an electrocardiogram (ECG) before a lacosamide dose increase above 400mg/day and after lacosamide is titrated to steady-state. In the placebo-controlled clinical studies of lacosamide in epilepsy patients, atrial fibrillation or flutter were not reported; however both have been reported in open-label epilepsy studies and in post-marketing experience. In post-marketing experience, AV block (including second degree or higher AV block) has been reported. In patients with proarrhythmic conditions, ventricular tachyarrhythmia has been reported. In rare cases, these events have led to asystole, cardiac arrest and death in patients with underlying proarrhythmic conditions. Patients should be made aware of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting). Patients should be counselled to seek immediate medical advice if these symptoms occur. Treatment with lacosamide has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine. New onset or worsening of myoclonic seizures has been reported in both adult and pediatric patients with primary generalized tonic-clonic seizures (PGTCS), in particular during titration. In patients with more than one seizure type, the observed benefit of control for one

seizure type should be weighed against any observed worsening in another seizure type. The safety and efficacy of lacosamide in pediatric patients with epilepsy syndromes in which focal and generalized seizures may coexist have not been determined. VIMPAT® syrup contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed). Vimpat Syrup contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age. Vimpat syrup contains propylene glycol (E1520). VIMPAT® syrup contains 1.42 mg sodium per ml, equivalent to 0.07 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. VIMPAT® solution for infusion contains 59.8 mg sodium per vial, equivalent to 3% of the WHO recommended maximum daily intake of 2 g sodium for an adult. **Effects on ability to drive and use machines**: Lacosamide may have minor to moderate influence on the ability to drive and use machines. Lacosamide treatment has been associated with dizziness or blurred vision. Accordingly, patients should be advised not to drive a car or to operate other potentially hazardous machinery until they are familiar with the effects of lacosamide on their ability to perform such activities. **Undesirable effects:** The most frequently reported adverse reactions (≥10%) are dizziness, headache, nausea and diplopia. 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, myoclonic seizures, ataxia, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, paresthesia, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, diarrhea, 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 and contusion. The use of lacosamide 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. 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, lacosamide should be discontinued. The safety profile of lacosamide in adjunctive therapy in pediatric patients with partial-onset seizures was consistent with the safety profile observed in adults. The additional adverse reactions observed in the pediatric population were pyrexia, nasopharyngitis, pharyngitis, decreased appetite, abnormal behavior and lethargy. Somnolence was reported more frequently in the pediatric population (≥ 1/10) compared to the adult population (≥ 1/100 to < 1/10).

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/vimpat-epar-product-information_en.pdf

Important Safety Information about RYSTIGGO® (rozanolixizumab-noli) in the US[6]

RYSTIGGO (rozanolixizumab-noli) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive.[6]

WARNINGS AND PRECAUTIONS

Infections: RYSTIGGO may increase the risk of infection. Delay RYSTIGGO administration in patients with an active infection until the infection is resolved. During treatment with RYSTIGGO, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding RYSTIGGO until the infection has resolved.

Immunization

Immunization with vaccines during RYSTIGGO treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because RYSTIGGO causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with RYSTIGGO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with RYSTIGGO.

Aseptic Meningitis: Serious adverse reactions of aseptic meningitis (also called drug-induced aseptic meningitis) have been reported in patients treated with RYSTIGGO. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and rash, were observed in patients treated with RYSTIGGO. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed.

ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of RYSTIGGO-treated patients) were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. Serious infections were reported in 4% of patients treated with RYSTIGGO. Three fatal cases of pneumonia were identified, caused by COVID-19 infection in two patients and an unknown pathogen in one patient. Six cases of infections led to discontinuation of RYSTIGGO.

The full Prescribing Information is available at https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf

Important Safety Information about ZILBRYSQ® (zilucoplan) in the US[Z]
IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

ZILBRYSQ is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.[7]

INDICATION

ZILBRYSQ (zilucoplan) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS
Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to administering the first dose of ZILBRYSQ, unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP)**

recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.

- **Persons receiving ZILBRYSQ are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for signs of meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

CONTRAINDICATIONS

ZILBRYSQ is contraindicated in patients with unresolved *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. The use of ZILBRYSQ increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

Complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to administering the first dose of ZILBRYSQ, according to current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.

If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with both MenACWY and MenB vaccines according to ACIP recommendations, administer meningococcal vaccine(s) as soon as possible and provide the patient with antibacterial drug prophylaxis.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection until the infection is resolved.

ZILBRYSQ REMS

Due to the risk of meningococcal infections, ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS.

Under the ZILBRYSQ REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines. Additional information on the REMS requirements is available at www.ZILBRYSQREMS.com or 1-877-414-8353.

Other Infections

ZILBRYSQ blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*.

Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae type b* (Hib) infections according to ACIP guidelines. Persons receiving ZILBRYSQ are at increased risk for infections due to these bacteria, even after vaccination.

Pancreatitis And Other Pancreatic Conditions

Pancreatitis and pancreatic cysts have been reported in patients treated with ZILBRYSQ. Patients should be informed of this risk before starting ZILBRYSQ. Obtain lipase and amylase levels at baseline before starting treatment with ZILBRYSQ. Discontinue ZILBRYSQ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of gMG patients treated with ZILBRYSQ) were injection site reactions, upper respiratory tract infections, and diarrhea.

The full Prescribing Information is available at https://www.ucb-usa.com/zilbrysq-prescribing-information.pdf

Important Safety Information about FINTEPLA® (fenfluramine) in the US[8]

INDICATIONS AND USAGE

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older.[8]

IMPORTANT SAFETY INFORMATION

BOXED WARNING: VALVULAR HEART DISEASE and PULMONARY ARTERIAL HYPERTENSION

- **There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension.**
- **Echocardiogram assessments are required before, during, and after treatment with FINTEPLA.**
- **FINTEPLA is available only through a restricted program called the FINTEPLA REMS.**

CONTRAINDICATIONS

FINTEPLA is contraindicated in patients with hypersensitivity to fenfluramine or any of the excipients in FINTEPLA and with concomitant use, or within 14 days of the administration, of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome.

WARNINGS AND PRECAUTIONS

Valvular Heart Disease and Pulmonary Arterial Hypertension (see Boxed Warning): Because of the association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease (VHD) and pulmonary arterial hypertension (PAH), cardiac monitoring via echocardiogram is required prior to starting treatment, during treatment, and after treatment with FINTEPLA concludes. Cardiac monitoring via echocardiogram can aid in early detection of these conditions. In clinical trials for DS and LGS of up to 3 years in duration, no patient receiving FINTEPLA developed VHD or PAH.

Monitoring: Prior to starting treatment, patients must undergo an echocardiogram to evaluate for VHD and PAH. Echocardiograms should be repeated every 6 months, and once at 3-6 months post treatment with FINTEPLA.

The prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA if any of the following signs are observed via echocardiogram: valvular abnormality or new abnormality; VHD indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation, with additional characteristics of VHD (eg, valve thickening or restrictive valve motion); PAH indicated by elevated right heart/pulmonary artery pressure (PASP >35 mmHg).

FINTEPLA REMS Program (see Boxed Warning): FINTEPLA is available only through a restricted distribution program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program. Prescribers must be certified by enrolling in the FINTEPLA REMS. Prescribers must counsel patients receiving FINTEPLA about the risk of VHD and PAH, how to recognize signs and symptoms of VHD and PAH, the need for baseline (pretreatment) and periodic cardiac monitoring via echocardiogram during FINTEPLA treatment, and cardiac monitoring after FINTEPLA treatment. Patients must enroll in the FINTEPLA REMS and comply with ongoing monitoring requirements. The pharmacy must be certified by enrolling in the FINTEPLA REMS and must only dispense to patients who are authorized to receive FINTEPLA. Wholesalers and distributors must only distribute to certified pharmacies. Further information is available at www.FinteplaREMS.com or by telephone at 1-877-964-3649.

Decreased Appetite and Decreased Weight: FINTEPLA can cause decreases in appetite and weight. Decreases in weight appear to be dose related. Approximately half of the patients with LGS and most patients with DS resumed the expected measured increases in weight during the open-label extension studies. Weight should be monitored regularly during treatment with FINTEPLA, and dose modifications should be considered if a decrease in weight is observed.

Somnolence, Sedation, and Lethargy: FINTEPLA can cause somnolence, sedation, and lethargy. Other central nervous system (CNS) depressants, including alcohol, could potentiate these effects of FINTEPLA. Prescribers should monitor patients for somnolence and sedation and should advise patients not to drive or operate machinery until they have gained sufficient experience on FINTEPLA to gauge whether it adversely affects their ability to drive or operate machinery.

Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including FINTEPLA, increase the risk of suicidal thoughts or behaviors in patients taking these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviors, or any unusual changes in mood or behavior.

Anyone considering prescribing FINTEPLA or any other AED must balance the risk of suicidal thoughts or behaviors with the risks of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behaviors. Should suicidal thoughts and behaviors emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Withdrawal of Antiepileptic Drugs: As with most AEDs, FINTEPLA should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse reaction, rapid discontinuation can be considered.

Serotonin Syndrome: Serotonin syndrome, a potentially life-threatening condition, may occur with FINTEPLA, particularly during concomitant administration of FINTEPLA with other serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), bupropion, triptans, dietary supplements (eg, St. John's Wort, tryptophan), drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors [MAOIs], which are contraindicated with FINTEPLA), dextromethorphan, lithium, tramadol, and antipsychotics with serotonergic agonist activity. Patients should be monitored for the emergence of signs and symptoms of serotonin syndrome, which include mental status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood pressure, hyperthermia), neuromuscular signs (eg, hyperreflexia, incoordination), and/or gastrointestinal symptoms (eg, nausea,

GL-BR-2400001 Date of preparation: April 2024

vomiting, diarrhea). If serotonin syndrome is suspected, treatment with FINTEPLA should be stopped immediately and symptomatic treatment should be started.

Increase in Blood Pressure: FINTEPLA can cause an increase in blood pressure. Rare cases of significant elevation in blood pressure, including hypertensive crisis, has been reported in adult patients treated with fenfluramine, including patients without a history of hypertension. In clinical trials for DS and LGS of up to 3 years in duration, no pediatric or adult patient receiving FINTEPLA developed hypertensive crisis. Monitor blood pressure in patients treated with FINTEPLA.

Glaucoma: Fenfluramine can cause mydriasis and can precipitate angle closure glaucoma. Consider discontinuing treatment with FINTEPLA in patients with acute decreases in visual acuity or ocular pain.

ADVERSE REACTIONS

The most common adverse reactions observed in DS studies (incidence at least 10% and greater than placebo) were decreased appetite; somnolence, sedation, lethargy; diarrhea; constipation; abnormal echocardiogram; fatigue, malaise, asthenia; ataxia, balance disorder, gait disturbance; blood pressure increased; drooling, salivary hypersecretion; pyrexia; upper respiratory tract infection; vomiting; decreased weight; fall; status epilepticus.

The most common adverse reactions observed in the LGS study (incidence at least 10% and greater than placebo) were diarrhea; decreased appetite; fatigue; somnolence; vomiting.

DRUG INTERACTIONS

Strong CYP1A2, CYP2B6, or CYP3A Inducers: Coadministration with strong CYP1A2, CYP2B6, or CYP3A inducers will decrease fenfluramine plasma concentrations. If coadministration of a strong CYP1A2, CYP2B6, or CYP3A inducer with FINTEPLA is necessary, monitor the patient for reduced efficacy and consider increasing the dosage of FINTEPLA as needed. If a strong CYP1A2, CYP2B6, or CYP3A inducer is discontinued during maintenance treatment with FINTEPLA, consider gradual reduction in the FINTEPLA dosage to the dose administered prior to initiating the inducer.

Strong CYP1A2 or CYP2D6 Inhibitors: Coadministration with strong CYP1A2 or CYP2D6 inhibitors will increase fenfluramine plasma concentrations. If FINTEPLA is coadministered with strong CYP1A2 or CYP2D6 inhibitors, the maximum daily dosage of FINTEPLA is 20 mg. If a strong CYP1A2 or CYP2D6 inhibitor is discontinued during maintenance treatment with FINTEPLA, consider gradual increase in the FINTEPLA dosage to the dose recommended without CYP1A2 or CYP2D6 inhibitors. If FINTEPLA is coadministered with stiripentol and a strong CYP1A2 or CYP2D6 inhibitor, the maximum daily dosage of FINTEPLA is 17 mg.

USE IN SPECIFIC POPULATIONS

In patients with severe impairment of kidney function (estimated glomerular filtration rate [eGFR]) 15 to 29 mL/min/1.73m^2, dosage adjustments are recommended. FINTEPLA has not been studied in patients with kidney failure (eGFR <15 mL/min/1.73m^2).

Combined molar exposures of fenfluramine and norfenfluramine were increased in subjects with various degrees of hepatic impairment (Child-Pugh Class A, B, and C), necessitating a dosage adjustment in these patients.

To report SUSPECTED ADVERSE REACTIONS, contact UCB, Inc. at 1-844-599-2273 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The full Prescribing Information is available at https://www.ucb.com/sites/default/files/2023-12/Fintepla_Current_COL_12_2023.pdf

Important Safety Information about BRIVIACT® (brivaracetam) CV in the US[9]

INDICATION

BRIVIACT® (brivaracetam) CV is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.[9]

IMPORTANT SAFETY INFORMATION

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. 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 in adult and pediatric patients. 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

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 were generally similar to those in adult patients. Adverse reactions with BRIVIACT injection in adult and pediatric patients were generally similar to those observed with BRIVIACT tablets. Other adverse events that

occurred in adult patients who received BRIVIACT injection included dysgeusia, euphoric mood, feeling drunk, and infusion site pain.

BRIVIACT is a Schedule V controlled substance.

The full Prescribing Information is available at:
https://www.ucb.com/_up/ucb_com_products/documents/Briviact-Full-Prescribing-Information-Rev-8.2021.pdf

Important Safety Information about VIMPAT® (lacosamide) CV in the US[10]

INDICATION
VIMPAT® is indicated for the treatment of partial-onset seizures in patients 1 month of age and older. VIMPAT is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.[10]

VIMPAT IMPORTANT SAFETY INFORMATION

VIMPAT is associated with important warnings and precautions including suicidal behavior and ideation, dizziness and ataxia, cardiac rhythm and conduction abnormalities, syncope, and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multi-organ hypersensitivity.

Partial-Onset Seizures
In the adult adjunctive placebo-controlled trials for partial-onset seizures, the most common adverse reactions (≥10% and greater than placebo) were dizziness, headache, nausea, and diplopia. In the adult monotherapy clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo-controlled trials, with the exception of insomnia (observed at a higher rate of ≥2%). Pediatric adverse reactions were similar to those seen in adult patients.

Primary Generalized Tonic-Clonic Seizures
In the adjunctive therapy placebo-controlled trial for primary generalized tonic-clonic seizures, the adverse reactions were generally similar to those that occurred in the partial-onset seizures trials. The adverse reactions most commonly reported were dizziness, somnolence, headache, and nausea.

The adverse reactions associated with VIMPAT injection in adult patients with primary generalized tonic-clonic seizures are expected to be similar to those seen in adults with partial-onset seizures. The adverse reactions associated with VIMPAT injection in pediatric patients are expected to be similar to those noted in adults. Infusion times less than 30 minutes were not adequately studied in pediatric patients.

VIMPAT contains lacosamide, a Schedule V controlled substance.
Please refer to the full Prescribing Information.

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.

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[1] RYSTIGGO® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf. (Accessed April 2024).
[2] ZILBRYSQ® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf. (Accessed April 2024).
[3] FINTEPLA® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf. (Accessed April 2024).
[4] BRIVIACT® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/briviact-epar-product-information_en.pdf. (Accessed: April 2024).
[5] VIMPAT® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/vimpat-epar-product-information_en.pdf. (Accessed: April 2024).
[6] RYSTIGGO® US PI. https://www.ucb.com/sites/default/files/2023-08/Rystiggo_Prescribing_Information_USA.pdf. (Accessed: April 2024).
[7] ZILBRYSQ® US PI. https://www.ucb.com/sites/default/files/2024-01/Zilbrysq_PI_27oct2023.pdf. (Accessed: April 2024).
[8] FINTEPLA ® US PI. https://www.ucb.com/sites/default/files/2023-12/Fintepla_Current_COL_12_2023.pdf. (Accessed: April 2024).
[9] BRIVIACT ® US PI. https://www.ucb-usa.com/briviact-prescribing-information.pdf. (Accessed: April 2024).
[10] VIMPAT ® US PI. https://www.ucb-usa.com/vimpat-prescribing-information.pdf. (Accessed: April 2024).