UCB News

UCB presents new data demonstrating quality-of-life impacts for epilepsy patients and caregivers at AAN 2026 meeting

- **Substantial impact of sleep disturbances:** New interim caregiver survey results found that a quarter of patients with developmental and epileptic encephalopathies (DEEs) experienced daily sleep disturbances, leading to a negative impact on activities of daily living and communication.[1]
- **Impact of prolonged seizures:** Results from global real-world data illustrate the impacts of prolonged seizures on both people living with epilepsy and their caregivers' ability to perform daily activities, with 88% and 96% respectively, reporting that seizures impacted their ability to perform normal daily activities.[2,3]
- **Benefits of persistence:** Claims analysis data evaluating treatment persistence with FINTEPLA®▼ [4,5] (fenfluramine) for people in the U.S. living with Lennox-Gastaut syndrome (LGS) show reductions in healthcare resource utilization and antiseizure medication claims for patients with treatment persistence at 6 and 12 months.[6]

Brussels (Belgium) 15 APRIL 2026, 07:00 (CET) – UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today presented new global, real-world, patient-centric data, including data from a study assessing the impacts on quality of life that developmental and epileptic encephalopathies (DEEs) have on individuals and caregivers, as well as the impact of living with prolonged seizures on patients and their caregivers. The company is presenting 21 abstracts in total from its innovative neurology portfolio (14 epilepsy abstracts, and seven rare abstracts including six myasthenia gravis (MG) abstracts) at the American Academy of Neurology (AAN) 2026 Annual Meeting (April 18-22, 2026).

New interim survey results demonstrated the impacts of sleep disturbances on activities of daily living (ADL) and communication[1]

Caregivers of people living with DEEs (n=489) – rare, severe, and lifelong epileptic syndromes[7] – completed an anonymous 63-question survey, providing information on sleep disruptions and their impact on activities of daily living (ADLs) and communication.

- Results demonstrated that 9.6% of patients' (n=47) sleep was "unpredictable with no typical pattern," while daily disruptive sleep was experienced by over a quarter of patients (27.0%; n=132).
- These sleep disturbances in approximately a quarter of patients (24.5%; n=120) were associated with temporary loss of one or more ADL and temporary loss of communication (21.5%; n=105), further underlining the impacts of sleep disruptions for these patients and their caregivers.

"Many people living with developmental and epileptic encephalopathies or DEEs experience significant sleep problems and behavioral difficulties, which can have real and long-lasting impacts on quality of life," **said Andrea Wilkinson, Global Head of Patient Engagement & Advocacy, Epilepsy & Neuromuscular, and lead author of the study**. "These results demonstrate the clear relationship between disrupted sleep and temporary losses in daily function and communications, underscoring the importance of addressing disease impacts beyond seizure alone and continuing to prioritize sleep as an endpoint in future research to improve outcomes."

Prolonged seizures impacted both patients and their caregivers' ability to perform daily activities with negative impacts on anxiety and depression[2,3]

Self-reported data from both people living with epilepsy and their caregivers illustrated the impacts of prolonged seizures.

- 88% of patients (n=438/498) and 96% of caregivers (n=270/282) reported that these seizures had impacted their ability to perform normal daily activities.
- Among patients (n=196) and caregivers (n=107), an average of 2.9 and 2.6 work hours per week, respectively, were missed due to prolonged seizures. Additionally, 79% of patients (n=181/229) and 94% of caregivers (n=157/167) reported that prolonged seizures negatively impacted their work productivity.
- Seizure worry also impacted both patients and caregivers, with over half of patients (58%; n=292/506) reporting they were at least slightly anxious/depressed, and almost a quarter (24%; n=62/263) of caregivers reporting a health condition developing or worsening due to their care of a patient with prolonged seizures.

A U.S. subgroup analysis of 545 patients with epilepsy who experienced ≥1 prolonged seizure (PS) evaluated seizure events, treatment use, healthcare resource utilization (HCRU), and overall disease burden. In this subgroup, 70% of patients were currently prescribed a rescue medication, 67% had a seizure action plan in place, and a higher proportion of patients required HCRU for their PS than their non-PS events. Seizure clusters and injuries were more commonly experienced among patients with PS events compared with non-PS events (14% vs. 9% and 21% vs. 17%, respectively), underscoring the need for additional treatment options to help prevent progression to more severe seizure states.

Treatment persistence with fenfluramine led to reductions in Healthcare Resource Utilization and antiseizure medication burden for people living with LGS in the U.S.[6]

Results from a retrospective analysis of people living with LGS in the U.S. using the Komodo U.S. healthcare claims database demonstrated that initiating fenfluramine was associated with reductions in HCRU and antiseizure medication (ASM) burden.

- Among patients with 12 months of fenfluramine continuous claims data before and after initiation (n=148), all-cause inpatient hospitalization claims decreased (mean 4.0 pre vs. 3.1 post; p=0.04), alongside reductions in seizure-related inpatient hospitalization claims (−23.6%; p=0.04), all-cause emergency room (ER) visit claims (−42.4%; p<0.01), seizure-related ER visit claims (−46.4%; p<0.01), and ambulance use claims (−61.8%; p<0.01).
- Patients who met the primary endpoint also experienced decreases in all ASM claims (−9.3%; p<0.01) and the average number of unique ASMs (−12.2%; p<0.01).
- In a broader cohort evaluating treatment persistence (n=544) with no fenfluramine gaps >90 days, fenfluramine persistence was 73% at 6 months and 61% at 12 months and the cohort treated with fenfluramine had a greater disease severity as indicated by number of comorbidities and HCRU, compared to the non-fenfluramine-treated cohort.

"Families living with LGS manage far more than seizures alone. Fewer emergency room visits, hospitalizations, and ambulance use can translate into less disruption, fewer crises and more stability for families," **said Hugo Xi, Head of US Medical Neurology**. "Seeing strong treatment persistence over time also reinforces that this therapy is fitting into real lives."

For further information, contact UCB:

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Global Communications
Anna Clark
T: +44 07386 686779
anna.clark@ucb.com

Corporate Communications, Media Relations
Laurent Schots
T +32.2.559.92.64
laurent.schots@ucb.com

Investor Relations
Antje Witte
T +32.2.559.94.14
antje.witte@ucb.com

Sahar Yazdian
T +32.2.559.94.37
sahar.yazdian@ucb.com

Yvonne Naughton
T +44.175.344.7521
yvonne.naughton@ucb.com

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 9000 people in approximately 40 countries, the company generated revenue of € 7.7 billion in 2025. UCB is listed on Euronext Brussels (symbol: UCB).

Forward-looking statements

This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "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 guaranteeing 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 be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

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Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, 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, supply chain disruption and business continuity risks; 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 or disruptive technologies/business models, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring, retention and compliance of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB'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, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving event or risk as mentioned above as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, 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.

Important Safety Information about FINTEPLA®▼ (fenfluramine) in the EU[4]

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. Paediatric 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

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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 coadministration with a strong CYP1A2 or CYP2D6 inhibitor may result in higher exposure (see section 4.4 of the SmPC). Coadministration 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. Pulmonary arterial hypertension: pulmonary arterial hypertension in a child associated with fenfluramine for Dravet syndrome has been reported post-marketing. The patient discontinued fenfluramine and the reaction resolved post-discontinuation. Valvular heart disease: valvular heart disease in a

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child associated with fenfluramine for Dravet syndrome has also been reported post-marketing (see 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. 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, seizure, status epilepticus, lethargy, tremor, constipation, salivary hypersecretion, blood prolactin increased, weight decreased, fall. Refer to SmPC for other adverse reactions.

▼ *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.*

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 (accessed October 2024)

Indication and Important Safety Information about FINTEPLA® (fenfluramine) in the US[5]

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.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: VALVULAR HEART DISEASE and PULMONARY ARTERIAL HYPERTENSION

- FINTEPLA can cause 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): FINTEPLA can cause valvular heart disease (VHD) and pulmonary arterial hypertension (PAH). Although no patients receiving FINTEPLA developed VHD or PAH in clinical trials for DS and LGS of up to 3 years in duration, cases of VHD and PAH have been reported during use of FINTEPLA in the postmarketing setting. Because of this risk, cardiac monitoring is required prior to starting treatment, during treatment, and after treatment with FINTEPLA concludes. Cardiac monitoring via echocardiogram can identify evidence of VHD and PAH prior to a patient becoming symptomatic, aiding in early detection of these conditions.

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 3-6 months post treatment with FINTEPLA.

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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 (e.g., valve thickening or restrictive valve motion); PAH indicated by elevated right heart/pulmonary artery pressure (PASP >35 mm Hg).

FINTEPLA REMS (see Boxed Warning): FINTEPLA is available only through a restricted distribution program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS). 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.

Decreased Appetite and Decreased Weight: FINTEPLA can cause decreases in appetite and weight. Decreases in weight appear to be dose related. 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 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.

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 (e.g., 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, autonomic instability, neuromuscular signs, and/or gastrointestinal symptoms. 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, have 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.

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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.

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.

Please see full Prescribing Information, including Boxed Warning and Medication Guide, for additional Important Safety Information on FINTEPLA.

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