

## UCB Completes Acquisition of Zogenix, Inc.

March 7, 2022

- Broadens and builds upon UCB's role as a leader in, and our continued commitment to, addressing unmet needs of people living with epilepsy
- Total transaction value of up to approximately US\$ 1.9 billion / € 1.7 billion. This consists of US\$ 26.00 in cash per Zogenix share plus a milestone-based contingent value right for a potential cash payment of US\$ 2.00 per share
- Acquisition is expected to contribute to UCB's revenue growth, be dilutive to 2022 earnings and be accretive to UCB's earnings from 2023 onwards. UCB's financial guidance to be updated during Q2 2022 as planned

BRUSSELS, Belgium and ATLANTA, March 7, 2022 /PRNewswire/ -- UCB (Euronext: UCB) today announced the successful completion of the previously announced transaction to acquire Zogenix (NASDAQ: ZGNX) for US\$ 26.00 per share plus a milestone-based contingent value right for a potential cash payment of US\$ 2.00 per share. The total transaction is valued at up to approximately US \$1.9 billion / €1.7 billion\*.



Charl van Zyl, Executive Vice President, Neurology & Head of Europe/International Markets, UCB, said: "We are very pleased to reach today's milestone at the earliest opportunity and to welcome the Zogenix team to the UCB family. We have a lot of important work ahead of us to deliver on our ambition of creating even greater value for people living with severe forms of epilepsy. Together we will bring FINTEPLA® (fenfluramine) oral solution to many more people around the world living with Dravet syndrome and, soon we hope, additional indications as well."

As of the tender offer expiration, the shares validly tendered and not withdrawn represented approximately 67% of Zogenix's outstanding shares. At the effective time of the merger, and subject to any perfected appraisal rights, all of the remaining shares of Zogenix common stock not purchased in the offer were cancelled and converted into the right to receive the same consideration per share offered in the tender offer. Pursuant to the terms of the merger agreement, Purchaser merged with and into Zogenix on 7 March 2022.

As a result of the merger, Zogenix has become a wholly-owned subsidiary of UCB and the common stock of Zogenix will be delisted from the NASDAQ Global Market.

### Financial guidance

UCB will update its financial guidance during Q2 2022 as planned. As announced earlier, UCB expects this acquisition to contribute to 2022 revenue immediately and to have a dilutive impact to the 2022 earnings. It is expected that the acquisition will be earnings accretive from 2023 onwards.

### About FINTEPLA® (fenfluramine) C-IV

FINTEPLA® (fenfluramine) oral solution is a prescription medication approved in the U.S. and Europe, and under regulatory review in Japan, for the treatment of seizures associated with Dravet syndrome in patients two years of age and older.<sup>1,2</sup> A Type II Variation Application has also been submitted to the European Medicines Agency (EMA), and a supplemental NDA is under priority review by the U.S. Food and Drug Administration (FDA).<sup>3,4</sup>

In the United States, FINTEPLA is available only through a restricted distribution program called the FINTEPLA REMS program. FINTEPLA is available in Europe under a controlled access program requested by the EMA to prevent off-label use for weight management and to confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking FINTEPLA. Further information is available at [www.FinteplaREMS.com](http://www.FinteplaREMS.com) or by telephone at +1 877 964 3649.

Please see full [Prescribing Information](#), including Boxed Warning, for additional important information on FINTEPLA.

### IMPORTANT SAFETY INFORMATION for FINTEPLA

#### BOXED WARNING: VALVULAR HEART DISEASE and PULMONARY ARTERIAL HYPERTENSION

- There is an association between serotonergic drugs with 5-HT<sub>2B</sub> 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 of, 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-HT<sub>2B</sub> receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension, 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 this condition. In clinical trials of up to 3 years in duration, no patient receiving FINTEPLA developed valvular heart disease or pulmonary arterial hypertension.

**Monitoring:** Prior to starting treatment, patients must undergo an echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypertension. Echocardiograms should be repeated every 6 months, and once at 3-6 months post treatment with FINTEPLA.

If valvular heart disease or pulmonary arterial hypertension is observed on an echocardiogram, the prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA.

**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 valvular heart disease and pulmonary arterial hypertension, how to recognize signs and symptoms of valvular heart disease and pulmonary arterial hypertension, 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](http://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. Most patients resumed the expected measured increases in weight by the end of the open-label extension study. 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) 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, 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. Significant elevation in blood pressure, including hypertensive crisis, has been reported rarely in adult patients treated with fenfluramine, including patients without a history of hypertension. Monitor blood pressure in patients treated with FINTEPLA. In clinical trials of up to 3 years in duration, no patient receiving FINTEPLA developed hypertensive crisis.

**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 (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.

To report SUSPECTED ADVERSE REACTIONS, contact Zogenix Inc. at +1 866 964 3649 (1-866-Zogenix) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## DRUG INTERACTIONS

Strong CYP1A2 and CYP2B6 Inducers: Coadministration with rifampin or a strong CYP1A2 and CYP2B6 inducer will decrease fenfluramine plasma concentrations. Consider an increase in FINTEPLA dosage when coadministered with rifampin or a strong CYP1A2 and CYP2B6 inducer.

## USE IN SPECIFIC POPULATIONS

Administration to patients with moderate or severe renal impairment or to patients with hepatic impairment is not recommended.

Please see full [Prescribing Information](#), including Boxed Warning, for additional important information on FINTEPLA.

### Footnote:

[\*Total transaction value fully diluted].

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## About UCB

UCB, Brussels, Belgium ([www.ucb.com](http://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 € 5.8

billion in 2021. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB\_news.

## Forward looking statements

This press release contains forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including but not limited to, the ability of UCB to successfully integrate the operations of Zogenix as planned or at all, 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, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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## References

1. FINTEPLA Summary of Product Characteristics. January 2022.
2. FINTEPLA® (fenfluramine) oral solution CIV.U.S. Prescribing Information.
3. Zogenix Press Release. Zogenix Submits Type II Variation Application to the European Medicines Agency (EMA) to Expand the Use of FINTEPLA® (Fenfluramine) for the Treatment of Seizures Associated with Lennox-Gastaut Syndrome.

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4. Zogenix Press Release. Zogenix Announces U.S. FDA Acceptance for Priority Review of Supplemental New Drug Application for FINTEPLA® (Fenfluramine) for the Treatment of Seizures Associated with Lennox-Gastaut Syndrome (LGS). Accessed 5 March 2022.

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