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Our Global Epilepsy Leadership

Charl van Zyl
Executive Vice President, Neurology Solutions & International Markets/Europe, UCB
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<th>Speaker</th>
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<td>Charl van Zyl</td>
<td>Our Epilepsy Leadership</td>
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<td>Mike Davis</td>
<td>Our Unified Epilepsy Strategy</td>
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<td>Konrad Werhahn, MD PhD</td>
<td>Fintepla®▼ (fenfluramine oral solution) Provides a New Set of Answers in Dravet &amp; Lennox Gastaut Syndrome</td>
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<td>Stefanie Dedeurwaerdere, PhD</td>
<td>Early Solutions: Leveraging Novel Science and Human Pathobiology for Improved Drug Targeting in Epilepsy</td>
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<td>Charl van Zyl</td>
<td>Summary: Evolution of UCB’s Epilepsy Pipeline into Precision Medicine with the Continued Ambition for Curative Therapy</td>
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<tr>
<td>All Speakers</td>
<td>Q&amp;A Session</td>
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Disclaimer: FINTEPLA is not approved in all geographies where we operate
Across UCB we are defined by our purpose:

Creating value for patients now and into the future and sustainability is our business approach.

We believe that everyone deserves to live the best life that they can - as free as possible from the challenges and uncertainty of disease.
UCB Epilepsy Leadership Across the Globe

UCB’s Portfolio of Epilepsy Solutions

Strategic Epilepsy Investments and Partnerships

UCB's Portfolio of Epilepsy Solutions

1. Keppra
2. VIMPAT®
3. BRIVIACT® (brivaracetam)
4. Nayzilam® (midazolam) nasal spray
5. Fintepla® (fenstetamine)

Worldwide epilepsy net sales

- >€3.0B\(^1\)

- >3.0M+ Epilepsy Patients under care worldwide

- 1 million compounds per drug screening

- >500+ protein targets reviewed

AI/digital pathobiology framework

- >250 interventional studies

- >25,000 patients enrolled

Full Year 2021: €3.238mn actual net sales as reported

\(^1\)Full Year 2021: €3.238mn actual net sales as reported
Our Unified Epilepsy Strategy

Mike Davis
Head of Global Epilepsy, UCB
Evolved UCB’s Organization

To Better Care for People Living with Epilepsy and Rare Syndromes

Key Drivers of Our Unified Epilepsy Strategy:

1. Maximizing – existing and future treatments
2. Innovative Science – new areas of science with a focus on specific unmet needs
3. Digital Health – investments to provide a more holistic level of treatment
4. Sustainable Value – driving access in a sustainable way; improving outcomes

Portfolio Focus

DISEASE MODIFICATION
DISEASE INTERACTION
TREATING SYMPTOMS

Digital & Patient Connectivity
Focus on seizure suppression
Improving quality of life & seizure freedom

Innovation
Moving patients towards underlying disease modification

Portfolio Focus Timeline:

Today
2
3
4
5
6
7
8
9
10
Timing (Years)
Paradigm Shift from Seizure Suppression to Disease Modification
From Broad Populations to Expansion into Specific Populations with High Unmet Patient Needs

Expression of Disease
Uncontrolled

Disease State Modification

Expansion from Treatment of Seizures to Targeting Molecular Disease

Pathobiology

TODAY
Novel SV2A and Na+ Channel Agents
UCB Leading Role

Disease State Understanding + Pathobiology / Translational Medicine

TOMORROW
More Targeted Therapies for Disease State Modification

Inspired by patients.
Driven by science.


**Epilepsy Innovation Strategy**

*Focused on Five Value Pools*

---

### Projected arrival in market of innovation focus areas

1. **Improved chronic ASM’s**
   - Optimize current portfolio through new formulations, indications and geographic expansion
   - Rare epilepsies: superior improvements in seizure frequency, comorbidities, and survival for DEE’s with FFA

2. **On-demand treatment**
   - Rapid cessation of prolonged seizure events within 2 mins
   - Leverage STAP as entry and explore to combine with seizure sensors

3. **Innovation pre-disease modification**
   - Accelerating disease-targeting pipeline through inorganic growth opportunities
   - Introduce first non-ASM Tx targeting disease denominator

4. **Disease modification**
   - Targeting underlying pathological cause of the epilepsy impacting disease trajectory

5. **Anti-epileptogenesis**
   - Therapies for prevention of epilepsy disease (e.g. in case of trauma induced epilepsy)

---

*AIE = autoimmune epilepsy, ASM = anti-seizure medication, DEE’s = developmental epileptic encephalopathies, FFA = fenfluramine, GT = gene therapy, STAP = Staccato alprazolam, KCNT1 = Potassium channel subfamily T, member 1*
FINTEPLA® (fenfluramine oral solution) Provides a New Set of Answers in Rare Epilepsy Syndromes

Konrad Werhahn, MD PhD
Epileptologist & Head of Global Epilepsy Medical Affairs, UCB

▼ 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. Licenses and approved indications for Fintepla® vary by country.
Fintepla® Important Safety Information

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®.

Summary of safety profile

The most commonly reported adverse reactions are decreased appetite, diarrhoea, pyrexia, fatigue, upper respiratory tract infection, lethargy, somnolence, and bronchitis.

Please see additional important safety information at: www.finteplahcp.com
“A parent’s worst nightmare”

Developmental and epileptic encephalopathies: a group of rare, severe and complex epilepsies

Typically occur in the **infancy and early childhood**

High frequency of **drug resistant seizures**

Associated with significant **intellectual, behavioural, physical and developmental delays**

High **risk of premature death** due to sudden unexpected death in epilepsy (SUDEP), fatal status epilepticus, and accidents

**Limited treatment options**

Dravet C, Epilepsia 2011;52 (S2):3–9; Raga et al., Epileptic Disord. 2021;23(1):40-52
Fenfluramine: What is the Value of a Unique and Dual MoA?

### Antiseizure effects

Anti-seizure effects mediated by multiple serotonergic receptors and sigma (σ) pathway activity
- 5-HT$_{1D}$, 5-HT$_{2A}$, 5-HT$_{2C}$ receptors$^{1,2}$
- Positive modulator of σ1 receptor$^{2,3}$

### Nonseizure effects

Improved memory and cognition via serotonergic and σ pathways
- 5-HT$_{4}$ agonists demonstrated pro-cognitive effects in both animal and human models$^{4-6}$
- Activity at σ1 receptors in mouse models$^{3}$

### SUDEP effects

Blocks seizure-induced respiratory arrest in a SUDEP mouse model via 5-HT$_{4}$ agonist activity$^{7}$

---

5-HT, 5-hydroxytryptamine; FFA, fenfluramine; GABA, gamma aminobutyric acid; SUDEP, sudden unexpected death in epilepsy.

Fenfluramine is indicated for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older.

Fenfluramine Offers New Hope for Individuals and Families Living with Challenging Developmental Epileptic Encephalopathies (DEEs)

<table>
<thead>
<tr>
<th>Dravet Syndrome (DS)</th>
<th>Lennox-Gastaut Syndrome (LGS)</th>
<th>CDKL5 Deficiency Disorder (CDD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>~12k-15k US, EU, JPN prevalence</td>
<td>~60k-100k US, EU, JPN prevalence</td>
<td>~8k-10k US, EU, JPN prevalence</td>
</tr>
<tr>
<td>&gt;80% of patients remain uncontrolled on existing AED regimens</td>
<td>Vast majority of patients on multi-drug treatment regimens of 2-5 ASMs as they experience multiple types of seizures, that change in type and frequency throughout life</td>
<td>Nearly three-quarters of individuals with CDD take 2 or more ASMs simultaneously</td>
</tr>
<tr>
<td>Premature childhood mortality, primarily SUDEP, of ~20%</td>
<td>Higher risk of status epilepticus and sudden death</td>
<td>&gt;70% of patients experience daily seizures</td>
</tr>
<tr>
<td>High risk of SUDEP</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Foundational Therapy**
- Profound impact on seizures exceeding expectations of what could be possible in DS

**The New Next Option**
- Proven efficacy on LGS’s most challenging seizures
- Proven efficacy as an adjunctive therapy

**Phase 3 trial ongoing, topline results H2 2024**
- Novel, complementary MOA with demonstrated impact on refractory seizure disorders

---

ASM, Antiseizure medications; CDKL5, Cyclin-dependent kinase-like 5; MOA, Mode of action; SUDEP: sudden unexpected death in epilepsy

Specchio et al., 2022, Epilepsia; Zuberi et al., 2022, Epilepsia. Licenses and approved indications for Fintepla® vary by country.
**Fenfluramine Creating Meaningful Value to Patients & HCPs across Dravet & Lennox-Gastaut Syndrome**

### Dravet Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Largest reduction in seizures associated with Dravet Syndrome</strong></td>
<td>– 1st or 2nd line recommendation in International DS Consensus.¹⁴</td>
</tr>
<tr>
<td><strong>Dramatically lowers seizures leading to SUDEP mortality compared to previous standard of care</strong></td>
<td>– All-cause and SUDEP mortality rate was 1.7 per 1000 person-years compared to 9.3 related to SUDEP alone for persons with DS receiving standard-of-care.⁴</td>
</tr>
<tr>
<td><strong>Improved everyday executive functioning</strong></td>
<td>Children and young adults who experienced a significant (&gt;50%) reduction of seizure frequency (78%) also showed improvement in emotional and cognitive regulation.⁶</td>
</tr>
</tbody>
</table>

### Lennox-Gastaut Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Profound seizure reduction in highest refractory population studied</strong></td>
<td>sustained for up to 15 months in added to current standard of care.⁴,¹³</td>
</tr>
<tr>
<td><strong>Substantial improvement in LGS-related cognitive and functional deficits</strong></td>
<td>– emotion, behavior, cognition and QoL.¹⁵</td>
</tr>
<tr>
<td><strong>Significant improvement in tonic-clonic seizures</strong></td>
<td>a primary risk factor for SUDEP.¹²,¹³</td>
</tr>
</tbody>
</table>

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Fenfluramine – In Their Words

"Fenfluramine has raised the bar for evaluating the efficacy of future therapies in Dravet syndrome, both for seizures and for critically important patient-centered outcomes." \(^2\)

"For the first time, it became possible for a large percentage of patients to achieve **profound reductions in convulsive seizure frequency**." \(^3\)

Generalized tonic-clonic seizures are commonly observed in patients with LGS. **The magnitude of response was similar to the reduction observed in patients with DS.**

"Improved everyday executive functioning following profound reduction in seizure frequency with fenfluramine." \(^4\)

"DS patients treated with FFA experienced a **substantially lower rate of all-cause and SUDEP-related mortality** compared with a historical natural history cohort." \(^1\)

**NNT=Number Needed to Treat. BRIEF, Behavior Rating Inventory of Executive Function; DS, Dravet syndrome; FFA, fenfluramine, MCSF, monthly convulsive seizure frequency; PAH, pulmonary arterial hypertension; VHD, valvular heart disease; \(^1\)Cross et al., Seizure 2021 Dec;93:154-159; \(^2\)Sullivan and Cross. Epilepsy Behavior 2021 Aug;121(Pt A):108061; \(^3\)Wirrell et al. Epilepsia 2022; 63(7):1761-1777; \(^4\)Bishop Kd et al. Epilepsy & Behavior 121 (2021) 108024**
Fenfluramine Open-Label Extension (LGS)
Frequency Reduction by Seizure Subtype (based on N=247 patients entering Open-Label Extension study)

- **GTCS**
  - Month 3: -59.8%
  - Month 6: -57.2%
  - Month 9: -56.4%
  - Month 12: -62.8%
  - Month 15: -79.1%

- **Tonic**
  - Month 3: -60.4%
  - Month 6: -62.6%
  - Month 9: -60.8%
  - Month 12: -67.7%
  - Month 15: -74.8%

- **Atonic**
  - Month 3: -43.6%
  - Month 6: -46.1%
  - Month 9: -46.3%
  - Month 12: -48.6%
  - Month 15: -50.9%

- **Tonic-Atonic**
  - Month 3: -57.2%
  - Month 6: -37.1%
  - Month 9: -38.3%
  - Month 12: -62.6%
  - Month 15: -64.5%

*versus randomized clinical trial baseline


Median Percentage Change in Seizure Frequency
Early Solutions Leveraging Novel Science and Human Pathobiology for Improved Drug Targeting in Epilepsy

Stefanie Dedeurwaerdere, PhD
Head of Epilepsy Discovery, UCB
How Could Treatments Become more Personalized?
How to Develop Treatments Tailored to Disease Mechanisms and Pathobiology?

In many patients, seizures are still not well controlled!

In many patients, seizures are not the only symptom!
Molecular Taxonomy – Focus on Etiology & Entry Points for Molecularly Targeted Treatments

Complex Epilepsy-Seizures

Upstream causal components can be identified for non-genetic complex epilepsies through investigation of pathobiology using digital/AI framework
UCB R&D Leveraging Human Pathobiology and Digital AI Framework in Epilepsy

UCB’s Differentiation*

- mRNA profiling of epilepsy samples
- Disease characterization
- Identification of disease regulatory mechanism
- Biological knowledge-relevance of disease models for transactional hypothesis

UCB R&D Epilepsy Engine

- mTLE, TSC, FCD Ila, GG, FCD IIb, DNT

- Identification of disease regulatory mechanism
  - Neuronal support and myelination
  - Brain extracellular matrix
  - Energy metabolism
  - Neuroinflammation and immune response

- Epilepsy platforms (Glia, CRISPR technology)

- Understanding of Epilepsy
  - Profiling Analysis
  -Canonical linear pathways

- Disease
  - Text mining

- Drugs
  - Therapeutic Landscape

- Gene expression
  - Pathways

R&D = research and development, mTLE = mesial temporal lobe epilepsy, TSC = tuberous sclerosis complex, FCD = focal cortical dysplasia, GG = ganglioglioma, DNT = developmental neuroepithelial tumor, CRISPR = clusters of regularly interspaced short palindromic repeats; *UCB internal assessment
Scientific Advances Combined with Digital Pathobiology are Driving Discovery Pipeline

**Patient segmentation** is based on a number of criteria...

- The targeted population has to be **identifiable** based on underlying pathobiology.
- The **unmet need** in the targeted population has to be large and the gain for patients high.

**Aside**

Monogenic diseases are of interest as they can be targeted at the root cause by **gene therapy and NCEs**.

...and driven by **scientific advances** in the field:

- Scientific maturity
- Potential for innovation
- UCB enabling discovery platforms
- Competitive edge

**Multiple Incubator projects**

- Several discovery pipeline assets including small molecule and gene therapy modalities
- NCE, new chemical entity; GT, gene therapy; DEE, Developmental and Epileptic Encephalopathy; KCNT1, Potassium channel subfamily T, member 1

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NCE, new chemical entity; GT, gene therapy; DEE, Developmental and Epileptic Encephalopathy; KCNT1, Potassium channel subfamily T, member 1

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Inspired by patients. Driven by science.
# UCB Late-Stage Pipeline in Neurology

Addressing Unmet Medical Needs and Bringing Clinically-Meaningful Improvements to People Living with Epilepsy and Neuroinflammatory & Neurodegenerative Diseases

<table>
<thead>
<tr>
<th>Rare Diseases</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Filing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Financing</strong></td>
<td>zilucoplan (C5 inhibitor)</td>
<td>Generalized myasthenia gravis</td>
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<td></td>
<td>rozanolizumab (FcRn inhibitor)</td>
<td>Generalized myasthenia gravis</td>
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<td></td>
<td>MOG-antibody disease</td>
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<td></td>
<td>Autoimmune encephalitis</td>
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<td></td>
<td>MT1621 (nucleoside therapy)</td>
<td>TK2 deficiency disorder</td>
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<tr>
<td></td>
<td>FINTEPLA® (fenfluramine; 5-HT agonist)</td>
<td>Lennox-Gastaut syndrome**</td>
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<td></td>
<td></td>
<td>Dravet syndrome**</td>
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<td>CDKL5 deficiency disorder</td>
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<td></td>
<td>STACCATO® alprazolam</td>
<td>Stereotypical prolonged seizures</td>
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<tr>
<td></td>
<td>bepranemab (anti-tau antibody)</td>
<td>Alzheimer’s disease***</td>
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<td></td>
<td>UCB0599 (α-syn-misfolding inhibitor)</td>
<td>Parkinson’s disease****</td>
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</tbody>
</table>

### Active Epilepsy Incubator and Early Discovery Pipeline

(multiple Incubator projects and several discovery pipeline assets including small molecule and gene therapy modalities)

<table>
<thead>
<tr>
<th>Neuroinflammation - autoantibody-mediated diseases</th>
<th>Mitochondrial diseases</th>
<th>Epilepsy</th>
<th>Neurodegeneration</th>
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<tr>
<td><strong>Epilepsy</strong></td>
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<tr>
<td><strong>Neurodegeneration</strong></td>
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</tbody>
</table>

*Launched in US; submitted in EU + other geographies; **Launched in US and EU; approved in Japan; submitted in other geographies; ***in partnership with Roche/Genentech; ****in partnership with Novartis; 5-HT - 5-hydroxytryptamin or serotonin; α-syn – alpha-synuclein; C5 – complement component 5; CDKL5 - cycle-dependent kinase-like 5; H – half-year; FcRn - Neonatal fragment crystallizable receptor; MOG - myelin oligodendrocyte glycoprotein; Q – quarter; SUDEP - sudden unexpected death in Epilepsy; TK2d - thymidine kinase 2 deficiency
UCB Continued Leadership in Epilepsy

Charl van Zyl
Executive Vice President, Neurology Solutions & International Markets/Europe, UCB
The Evolution of UCB’s Epilepsy Pipeline into Precision Medicine with the Continued Ambition for Curative Therapy

Digitized End-to-End Model (Patient-centric Business) - from Discovery to Patients

**Commitment to Patients, Research and Education**
- Move from molecules aimed to increase the suppression of seizures to targeting pathobiology
- Expansion into causal components of epilepsies with greatest unmet needs

**Precision Medicine**
- Developing drugs to modulate the pathways identified
- Greater specificity at molecular level allows for expansion into personalized therapies

**Translational Medicine**
- Ensuring transfer of the science based on pathobiology to loadable clinical endpoints and value for patients

**Drug Discovery**
- Identify targets and candidate therapies that modulate critical pathways responsible for causal components of epilepsy
UCB Leading in Epilepsy

Epilepsy remains a core pillar of UCB’s strategy to bring differentiated value to patients

- Elevating care for the patient populations we serve
- Innovating science for symptom suppression, disease modification and cure
- Leading the wider ecosystem
Antje Witte
Head of Investor Relations, UCB

Charl van Zyl
Executive Vice President
Neurology Solutions
& Head of EU and International Markets

Mike Davis
Head of Global Epilepsy, UCB

Konrad Werhahn, MD, PhD
Head of Medical Affairs, Epileptologist, UCB

Stefanie Dedeurwaerdere, PhD
Head of Epilepsy Discovery, UCB
Thank you