UCB News

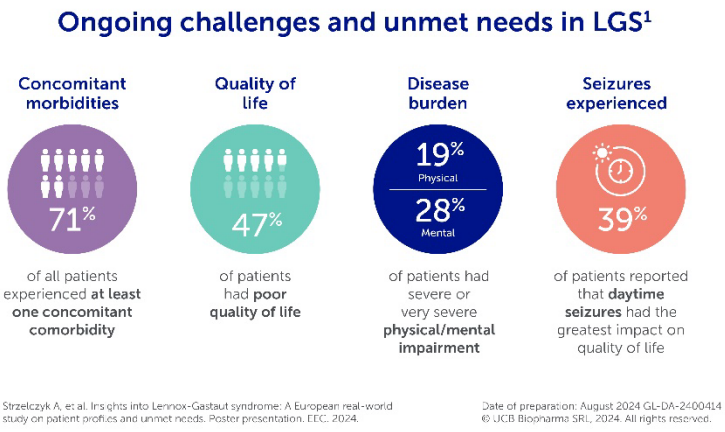
New insights highlight unmet needs for people living with Lennox-Gastaut syndrome and significant burden of the disease

- New data presented at the 15th European Epilepsy Congress highlight lengthy delays in Lennox-Gastaut syndrome (LGS) diagnosis in Europe and significant disease burden from both seizure and non-seizure impairments[1]
- LGS is a severe childhood-onset developmental and epileptic encephalopathy, a group of epilepsies associated with developmental impairment, which is characterized by several different seizure types[2]
- New treatment options are needed to improve the long-term prognosis of individuals with LGS[3]

Brussels, Belgium – Monday 9th September 2024 – 7:00 CET – The need for quicker and more accurate Lennox-Gastaut syndrome (LGS) diagnoses was highlighted today in a European real-world study presented at the 15th European Epilepsy Congress using data from the Adelphi LGS Disease Specific Programme™ (DSP). Data from 454 pediatric and adult LGS patients across Europe reported it takes on average 12.3 months to receive a correct LGS diagnosis, following the first seizure at 4 years old (mean average age), exposing the lengthy wait patients and their families face for a correct diagnosis in Europe.[1]

Despite patients receiving more than three (3.4) antiseizure medications on average each day, ongoing challenges in effectively treating LGS remain[1]:

- 71% of patients (N=324/454) experienced at least 1 concomitant comorbidity, with the most frequently reported including psychomotor or cognitive impairment, attention deficit hyperactivity disorder (ADHD), sleep disorder or insomnia
- 19% and 28% of patients experienced severe or very severe physical and mental impairment, respectively, many of which persist with age
- 47% of patients were reported to have at least somewhat poor quality of life
- Daytime seizures were reported to have the greatest impact on quality of life for 39% of patients



These findings underline the need for new treatments that can target both drug-resistant seizures and the non-seizure symptoms of LGS.

Inspired by patients.
Driven by science.

Dr Konrad Werhahn, Global Medical Affairs, UCB, said: "The impact of LGS goes beyond seizures and can include severe cognitive impairment, communication difficulties, psychiatric symptoms, behavioral challenges, and mobility problems, all of which constitute a major burden for patients and their caregivers/families. At UCB, we understand the need for a multidisciplinary, individualized approach to care which addresses each patient's medical, educational, psychological, and social needs throughout the course of their life."

LGS affects approximately one million people worldwide.[4] However, diagnosis remains complex and challenging due to the lack of specific biological markers for the condition, multiple possible causes, and varied presentation of symptoms.[2]

Although several approved drugs are available for LGS, there are still unmet needs for treatment. These drugs provide an improvement, but usually not with a sustained long-term effect, resulting in a need for novel therapies which effectively target seizures and alleviate non-seizure outcomes to enhance the prognosis for patients with LGS.[3]

Diagnostic aid for healthcare professionals

In addition, at the EEC, details of a new LGS electronic decision-assisting tool based on International League Against Epilepsy (ILAE) diagnostic criteria were presented. Developed by a group of ten epilepsy experts, its digitalization has been funded by UCB (with no influence on its content), the tool is designed to help physicians evaluate the likelihood that their patient has LGS. The questionnaire considers the mandatory, alert, and exclusionary features of LGS, providing a result that will guide future management.[5,6] The prototype will now be tested and validated prior to use by healthcare professionals in the clinical setting.

For further information, contact UCB:

Global Communications
Nick Francis
T: +44 7769 307745
nick.francis@ucb.com

Corporate Communications
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

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 9,000 people in approximately 40

countries, the company generated revenue of €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements

This press release may contain forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: the global spread and impact of COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products, which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular

time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

References:

[1] Strzelczyk A, Gil-Nagel A, Striano P et al. Insights into Lennox-Gastaut syndrome: A European real-world study on patient profiles and unmet needs. Poster presented at: The 15th European Epilepsy Congress (EEC); 2024, September 7-11; Rome, Italy.
[2] Bourgeois BFD, Douglass LM, Sankar R. et al Lennox-Gastaut syndrome: A consensus approach to differential diagnosis. Epilepsia. 2014;55(Suppl 4):4-9.
[3] Auvin S. Lennox-Gastaut syndrome: New treatments and treatments under investigation. Rev Neurol (Paris). 2020;176(6):444-7.
[4] LGS Foundation. Factsheet: What is LGS? https://www.lgsfoundation.org/wp-content/uploads/2024/05/Updated-MAY-2024.png. Last accessed: July 2024.
[5] Arzimanoglou A, Specchio N, Auvin S et al. Development of an Electronic Diagnostic Criteria Tool for Lennox-Gastaut Syndrome (LGS). Poster presented at: The 15th European Epilepsy Congress (EEC); 2024, September 7-11; Rome, Italy.
[6] Specchio N, Wirrell EC, Scheffer IE, et al. ILAE Classification and Definition of Epilepsy Syndromes with Onset in Childhood: Position Paper by the ILAE Task Force on Nosology and Definitions. Epilepsia. 2022;63(6):1398-442.