# Jazz Pharmaceuticals to Present Extensive New Data and Real-World Evidence Highlighting Epidiolex® (cannabidiol) Outcomes in Treatment-Resistant Epilepsies at the American Epilepsy Society 2025 Annual Meeting

December 05, 2025

*New interim results from the EpiCom trial, a prospective evaluation of behavioral outcomes in patients with tuberous sclerosis complex, suggest improvements in non-seizure outcomes*

*Eight abstracts, including four late-breaking abstracts, underscore Jazz's continued commitment to the epilepsy community and advancing the comprehensive treatment for rare forms of epilepsy*

*For U.S. media and investors only*

DUBLIN, Dec. 5, 2025 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that eight abstracts, including four that are late-breaking, will be presented on Epidiolex® (cannabidiol) at the American Epilepsy Society (AES) 2025 Annual Meeting, being held December 5-9, 2025, in Atlanta, Georgia.

Notable data include new results from the EpiCom trial, an ongoing Phase 3b/4 study evaluating behavioral and other non-seizure outcomes after initiation of adjunctive *Epidiolex* treatment in participants with tuberous sclerosis complex (TSC)-associated seizures. Notably, the prespecified 6-month intermediate analysis of EpiCom demonstrated promising reductions in the TSC–Associated Neuropsychiatric Disorders Self-Report Quantified Checklist (TAND-SQ) and Aberrant Behavior Checklist (ABC) subscale scores, as well as in the severity of behavioral problems reported by caregivers and clinicians after 26 weeks of *Epidiolex* treatment.

"We are proud to share extensive research at AES 2025, including findings from the innovative EpiCom trial which utilized novel endpoints focused on individualized outcomes, including each participant's respective most problematic behavior as identified by caregivers and clinicians to ensure our research addresses the priorities of those we serve," said Jessa Alexander, Ph.D., neuroscience therapeutic area head, global medical and scientific affairs of Jazz Pharmaceuticals. "Data from EpiCom and real-world insights continue to expand our understanding of the complex realities faced by patients living with rare epilepsy disorders while further underscoring *Epidiolex's* ability to contribute to meaningful, holistic management."

Additional highlights at AES 2025 include:

- A late-breaking poster featuring results from a Phase 1 clinical study evaluating bidirectional pharmacokinetic (PK) drug-drug interactions between *Epidiolex* and cenobamate, which did not find PK interactions between cannabidiol and cenobamate parent molecules when concomitantly administered at clinically relevant dosages.
- A late-breaking poster showcasing preclinical data that demonstrates a novel synergistic pharmacodynamic interaction between *Epidiolex* and cenobamate in effectiveness in the mouse maximal electroshock seizure model of acute generalized seizures.
- Two presentations highlight real-world effectiveness of *Epidiolex* using data from the U.S. Optum® Market Clarity Database (an integrated electronic health record and claims database). One late-breaking poster features data that shows *Epidiolex* initiation in CBD-naïve patients with Dravet Syndrome (DS), LGS or TSC is associated with reduced polypharmacy and healthcare resource utilization (HCRU) at 12 months, with further reductions among early-line *Epidiolex* initiators. The other poster highlights data that indicates *Epidiolex* initiation also reduces antiseizure medication cycling at 12 months, as well as decreased polypharmacy and HCRU in both pediatric and adult patients.
- A poster presentation featuring post-hoc analysis from the Expanded Access Program demonstrates *Epidiolex* treatment is associated with reductions in convulsive and total seizure frequency in patients with developmental and epileptic encephalopathies (DEEs) and rare epilepsy syndromes. The comparative effectiveness analysis confirms the superiority of *Epidiolex* in reducing seizure frequency from baseline compared to an external placebo control arm.
- A poster presentation highlighting a subgroup analysis of *Epidiolex* pivotal clinical trial data showing participants with Lennox-Gastaut syndrome (LGS) diagnoses, which are secondary to a genetic DEE, experienced consistent efficacy and safety as compared to the overall LGS pivotal trial populations.
- A late-breaking poster presentation on data from the Epilepsy Learning Healthcare System (ELHS), an Epilepsy Foundation-sponsored initiative, highlights its potential to provide real-world treatment insights beyond clinical trials and claims data.

All AES 2025 abstracts are available online at the following link: aesnet.org/education/annual-meeting/aes-abstract-search.

A full list of Jazz Pharmaceuticals' presentations follows below:

| Presentation Title | Presenting Author | Poster Details \| Date & Time (ET) |
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| Cannabidiol Efficacy in Patients With Lennox-Gastaut Syndrome With Developmental and Epileptic Encephalopathy-Associated Genetic Variants: A Subgroup Analysis | E Thiele | Poster Number: 1.382<br>Session Date/Time: Saturday December 6, 12:00-2:00pm |
| Phase 1, Open-Label, Fixed-Sequence, Bidirectional, Pharmacokinetic Drug-Drug Interaction Study Between Cannabidiol and Cenobamate in Healthy Adult Participants | A Vijan | Poster Number: 1.545<br>Session Date/Time: Saturday December 6, 12:00-2:00pm |
| An Assessment of Acute Pharmacodynamic Drug-Drug Interactions Between Cannabidiol and Cenobamate in a Mouse Model of Generalized Tonic Seizures | W Hind | Poster Number: 1.546<br>Session Date/Time: Saturday December 6, 12:00-2:00pm |
| A Population Health Study of Patients Prescribed Cannabidiol in the Epilepsy Learning Healthcare System (ELHS) Registry | KM Farrell | Poster Number: 1.549<br>Session Date/Time: Saturday December 6, 12:00-2:00pm |
| Effectiveness of Cannabidiol in Patients With Rare Epilepsies Compared to External Placebo Control: A Post-Hoc Analysis From the Expanded Access Program | Y Park | Poster Number: 2.337<br>Session Date/Time: Sunday December 7, 12:00-2:00pm |
| Real-World Polypharmacy and Healthcare Resource Utilization After Early-Line Treatment With Cannabidiol for Lennox-Gastaut Syndrome, Dravet Syndrome, and Tuberous Sclerosis Complex | M Navetta | Poster Number: 2.433<br>Session Date/Time: Sunday December 7, 12:00-2:00pm |
| Tuberous Sclerosis Complex (TSC)–Associated Neuropsychiatric Disorders (TAND) Outcomes Following Adjunctive Cannabidiol (CBD) Treatment: 6-Month Intermediate Analysis of the EpiCom Trial | J Stevens | Poster Number: 3.351<br>Session Date/Time: Monday December 8, 12:00-1:45pm |
| Real-World Effectiveness of Cannabidiol on Antiseizure Medication Cycling, Polypharmacy, and Healthcare Resource Utilization: A US Claims Analysis | A Sillah | Poster Number: 3.368<br>Session Date/Time: Monday December 8, 12:00-1:45pm |

**About Tuberous Sclerosis Complex**

Tuberous sclerosis complex (TSC) is a rare genetic condition.[1] The condition causes mostly benign tumors to grow in vital organs of the body including the brain, skin, heart, eyes, kidneys and lungs[2] and is a leading cause of genetic epilepsy.[3] People with TSC may experience a variety of seizure types. One of the most common is infantile spasms that typically present in the first year of life; focal (or partial) seizures are also very common.[4] TSC is associated with an increased risk of autism and intellectual disability[5] and the severity of the condition can vary widely. In some children the disease is very mild, while others may experience life-threatening complications.[4] Epilepsy is present in about 85% of patients with TSC and may progress to become intractable to medication.[4,6,7] More than 60% of individuals with TSC do not achieve seizure control[8] with standard treatments such as antiepileptic drugs, epilepsy surgery, ketogenic diet, or vagus nerve stimulation[8] compared to 30%-40% of individuals with epilepsy who do not have TSC who are drug resistant.[9,10]

**About Dravet Syndrome**

Dravet syndrome (DS) is a rare genetic condition that appears during the first year of life with frequent fever-related seizures (febrile seizures). Later, other types of seizures typically arise, including myoclonic seizures (involuntary muscle spasms).[11] Additionally, status epilepticus, a potentially life-threatening state of continuous seizure activity requiring emergency medical care, may occur. Children with DS typically experience poor development of language and motor skills, hyperactivity and difficulty relating to others.

**About Lennox-Gastaut Syndrome**

Lennox-Gastaut syndrome (LGS) begins in childhood. It is characterized by multiple types of seizures. People with LGS begin having frequent seizures in early childhood, usually between ages 3 and 5.[12] More than three-quarters of affected individuals have tonic seizures, which cause the muscles to contract uncontrollably. Almost all children with LGS develop learning problems and intellectual disability. Many also have delayed development of motor skills such as sitting and crawling. Most people with LGS require help with usual activities of daily living.

**About Epidiolex®/Epidyolex® (cannabidiol)**

*Epidiolex/Epidyolex* is a prescription, plant-derived cannabis-based medicine administered as an oral solution which contains highly purified cannabidiol (CBD). Cannabidiol, the active ingredient in *Epidiolex*, is a cannabinoid that naturally occurs in the *Cannabis sativa* L. plant. The precise mechanisms by which *Epidiolex* exerts its anticonvulsant effect in humans are unknown. *Epidiolex* was approved by the U.S. Food and Drug Administration (FDA) for use in the U.S., the European Commission (EC) for use in Europe, the Medicines and Healthcare products Regulatory Agency (MHRA) for use in Great Britain, the Therapeutic Goods Administration for use in Australia, Swissmedic for use in Switzerland, the Food & Nutrition Services of the Israel Ministry of Health for use in Israel, and the New Zealand Medicines and Medical Devices Safety Authority for use in New Zealand, is an oral solution which contains highly purified cannabidiol (CBD). In the U.S., *Epidiolex* is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex (TSC) in patients one year of age and older. *Epidiolex* has received approval in the European Union under the tradename *Epidyolex* for adjunctive use in conjunction with clobazam to treat seizures associated with LGS and DS in patients two years and older, and for adjunctive use to treat seizures associated with TSC, in patients two years of age and older. *Epidiolex* has received Orphan Drug Designation (ODD) from the U.S. FDA for the treatment of seizures associated with LGS, DS, and TSC. Similarly, *Epidyolex* received ODD from the European Medicines Agency (EMA) for the same indications. *Epidiolex* is also being studied in additional forms of epilepsy, including the EpiFOS exploratory study (NCT07233239) in focal-onset seizures.

**Important Safety Information & Indications**

**CONTRAINDICATION: HYPERSENSITIVITY**

EPIDIOLEX (cannabidiol) oral solution is contraindicated in patients with a history of hypersensitivity to cannabidiol or any ingredients in the product.

**WARNINGS & PRECAUTIONS**

**Hepatic Injury:**
EPIDIOLEX can cause dose-related transaminase elevations. Concomitant use of valproate and elevated transaminase levels at baseline increase this risk. Obtain transaminase and bilirubin levels prior to starting treatment, at 1, 3, and 6 months after initiation of treatment, and periodically thereafter, or as clinically indicated. Resolution of transaminase elevations occurred with discontinuation of EPIDIOLEX, reduction of EPIDIOLEX and/or concomitant valproate, or without dose reduction. For patients with elevated transaminase levels, consider dose reduction or discontinuation of EPIDIOLEX or concomitant medications known to affect the liver (e.g., valproate or clobazam). Dose adjustment and slower dose titration is recommended in patients with moderate or severe hepatic impairment. Consider not initiating EPIDIOLEX in patients with evidence of significant liver injury. There have been postmarketing reports of cholestatic or mixed patterns of liver injury. Elevated ammonia levels were reported in some patients with transaminase elevations; most taking concomitant valproate, clobazam, or both. Consider discontinuation or dose adjustment of valproate or clobazam if ammonia is elevated.

**Somnolence and Sedation:**
EPIDIOLEX can cause somnolence and sedation that generally occurs early in treatment and may diminish over time; these effects occur more commonly in patients using clobazam and may be potentiated by other CNS depressants.

**Suicidal Behavior and Ideation:**
Antiepileptic drugs (AEDs), including EPIDIOLEX, increase the risk of suicidal thoughts or behavior. Inform patients, caregivers, and families of the risk and advise them to monitor and report any signs of depression, suicidal thoughts or behavior, or unusual changes in mood or behavior. If these symptoms occur, consider if they are related to the AED or the underlying illness.

**Withdrawal of Antiepileptic Drugs:**
As with most AEDs, EPIDIOLEX should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

**ADVERSE REACTIONS:**
The most common adverse reactions in patients receiving EPIDIOLEX (≥10% and greater than placebo) include transaminase elevations; somnolence; decreased appetite; diarrhea; pyrexia; vomiting; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor-quality sleep; and infections. Hematologic abnormalities were also observed.

**PREGNANCY:**
EPIDIOLEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Encourage women who are taking EPIDIOLEX during pregnancy to enroll in the EPIDIOLEX Pregnancy Surveillance Program and the North American Antiepileptic Drug (NAAED) Pregnancy Registry.

**DRUG INTERACTIONS:**
Strong inducers of CYP3A4 and CYP2C19 may affect EPIDIOLEX exposure. EPIDIOLEX may affect exposure to CYP2C19 substrates (e.g., clobazam, diazepam, stiripentol), orally administered P-gp substrates, or other substrates (see full Prescribing Information). Consider dose reduction of orally administered everolimus, with appropriate therapeutic drug monitoring, when everolimus is combined with EPIDIOLEX. A lower starting dose of everolimus is recommended when added to EPIDIOLEX therapy. Concomitant use of EPIDIOLEX and valproate increases the incidence of liver enzyme elevations. Pneumonia was observed more frequently with concomitant use of EPIDIOLEX and clobazam. Dosage adjustment of EPIDIOLEX or other concomitant medications may be necessary.

**INDICATIONS:**
EPIDIOLEX (cannabidiol) oral solution is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

**Please read the EPIDIOLEX full Prescribing Information for additional important information here.**

**About Jazz Pharmaceuticals**
Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharma company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing potentially life-changing medicines for people with serious diseases — often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience. Jazz is headquartered in Dublin, Ireland with research and development laboratories, manufacturing facilities and employees in multiple countries committed to serving patients worldwide. Please visit www.jazzpharmaceuticals.com for more information.

**Contacts:**

**Media:**
Kristin Bhavnani
Head of Global Corporate Communications
Jazz Pharmaceuticals plc
CorporateAffairsMediaInfo@jazzpharma.com
Ireland +353 1 637 2141
U.S. +1 215 867 4948

**Investors:**
Jack Spinks
Executive Director, Investor Relations
Jazz Pharmaceuticals plc
investorinfo@jazzpharma.com
Ireland +353 1 634 3211
U.S. +1 650 496 2717

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