3.351 Tuberous Sclerosis Complex (TSC)–Associated Neuropsychiatric Disorders (TAND) Outcomes Following Adjunctive Cannabidiol (CBD) Treatment: 6-Month Intermediate Analysis of the EpiCom Trial

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Introduction

- Approximately 90% of people with tuberous sclerosis complex (TSC) experience TSC-associated neuropsychiatric disorders (TAND; **Figure 1**), which substantially impact their quality of life. However, treatment options remain limited[1,2]
- A plant-derived, highly purified pharmaceutical formulation of cannabidiol (CBD; Epidiolex® [US]/ Epidyolex® [EU]) is approved for the treatment of seizures associated with TSC[3,4]
- Anecdotal reports from the TSC community of patients, caregivers, and healthcare professionals have suggested benefits with CBD treatment in behavioral (eg, calm or relaxed behavior) and neuropsychological symptoms (eg, increased attention span, awareness, and concentration)[5]
- EpiCom (**Epi**lepsy **Com**orbidities; NCT05864846) is an interventional, multicenter, open-label, single-arm, phase 3b/4 study evaluating behavioral and other co-occurring outcomes following adjunctive CBD treatment in participants with TSC-associated seizures[5]

Figure 1. TAND clusters[6]

Assessment of TAND

The **TAND Self-Report Quantified Checklist (TAND-SQ)**, developed by the TAND consortium, is a validated tool designed to capture behaviors and quantify the severity of TAND difficulties[6-8]

- It consists of 33 items representing 7 natural TAND clusters and an eighth cluster addressing psychosocial difficulties experienced by individuals with TSC and their caregivers[6,7]
- Respondents report whether each item has ever been present and rate item severity (over the last month) on an 11-point numerical rating scale ranging from 0 (not at all) to 10 (extremely), to generate **cluster severity scores** and a **total TAND severity score**[7,8]
- **Most problematic behavior (MPB)** is defined as the single behavior identified by the caregiver as most troublesome for the participant based on the TAND-SQ checklist[8]

Objective

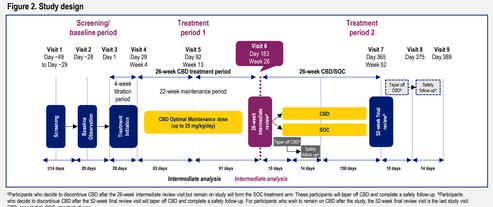
To investigate behavioral and other co-occurring outcomes after initiation of treatment with adjunctive CBD in patients with TSC-associated seizures. Here, we present the prespecified 6-month intermediate analysis of EpiCom

Methods

- Eligible participants aged 1 to 65 years[a] with TSC-associated seizures and experiencing moderate/severe behavioral challenges on the Caregiver Global Impression of Severity (CareGI-S) scale were enrolled (**Table 1**)
- After a screening and baseline period of up to 49 days, participants receive CBD ≤25 mg/kg/day (based on response and tolerability) in addition to standard of care (SOC) for 26 weeks (Treatment period 1) (**Figure 2**)
  - The 26-week CBD treatment period includes a 4-week titration period and 22-week maintenance period
  - After 26 weeks on CBD + SOC, participants choose to continue either CBD with SOC or SOC alone for an additional 26 weeks (Treatment period 2)
- This 6-month intermediate analysis includes enrolled participants (n=79) who completed Treatment period 1 (Visit 6) as of April 2025 (n=28)
  - All enrolled participants received ≥1 dose of CBD and were included in the safety analysis set
  - ≥1 postbaseline assessment was available for 62 participants, who were included in the full analysis set
- Key endpoints evaluated at the 26-week intermediate analysis were:
  - MPB, TAND-SQ, Aberrant Behavior Checklist (ABC), CareGI-S, Clinician Global Impression of Severity (CGI-S), Child and Adult Behavior Checklist (CBCL/ABCL), seizure outcomes, treatment-emergent adverse events (TEAEs), and serious adverse events (SAEs)
  - Data were analyzed using standard descriptive statistics for continuous variables, including 95% CI for mean and median changes
- The EpiCom study was conducted with Epidiolex®/Epidyolex®, and results do not apply to other CBD-containing products, which are not FDA approved for the treatment of seizures associated with TSC

[a]Eligible participants were aged 2-65 years in the United Kingdom, Canada, and Poland.

Figure 2. Study design



[b]Participants who decide to discontinue CBD after the 26-week intermediate review visit but remain on study will form the SOC treatment arm. These participants will taper off CBD and complete a safety follow-up. [c]Participants who decide to discontinue CBD after the 52-week final review visit will taper off CBD and complete a safety follow-up. For participants who wish to remain on CBD after the study, the 52-week final review visit is the last study visit. CBD, cannabidiol; SOC, standard of care.

Table 1. Key inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
• **Confirmed diagnosis of TSC** with a history of seizures • **Moderate/severe behavioral challenges** (eg, aggression, impulsivity, temper tantrums, self-injury, and hyperactivity), with a most problematic behavior score of ≥6 on the TAND-SQ at baseline[a] • On **≥1 antiseizure medication** • **Naive to CBD** or has been off CBD for ≥3 months before screening	• Any medical condition that could affect study outcomes • Felbamate initiation within the year before screening • Use of cannabis or cannabinoid-based products within the 3 months before screening • Significant hepatic impairment and any history of suicidal behavior or ideation of type 4 or 5 as evaluated by the Columbia-Suicide Severity Rating Scale

[a]Based on the Likert scale: 1 = Very unimportant; 5 = Neither important nor unimportant; and 10 = Extremely important
CBD, cannabidiol; TAND, TSC-associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist; TSC, tuberous sclerosis complex.

Results

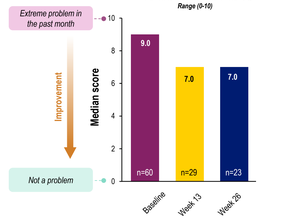
Table 2. Patient disposition and baseline characteristics

	CBD (N=79)
Age, years	
Mean (SD)[a]	18.5 (10.32)
Median (range)	16.0 (3–42)
Sex, n (%)	
Male	46 (58.2)
Female	33 (41.8)
Race, n (%)	
White	70 (88.6)
Asian	3 (3.8)
Black or African American	3 (3.8)
Declined to state	3 (5.3)
American Indian or Alaska Native	0
Native Hawaiian or other Pacific Islander	0
Multiple	0
Ethnicity, n (%)	
Hispanic or Latino	10 (12.7)
Not Hispanic or Latino	69 (87.3)
Number of participants reporting seizures within 12 months prior to screening, n (%)[b]	56 (70.9)
Average number of seizures per 28 days at baseline, mean (SD)[b]	20.4 (47.7)
Number of ASMs at baseline, median (range)	2 (0-6)
Most common baseline ASMs, n (%)	
Lamotrigine	24 (30.4)
Midazolam[c]	18 (22.8)
Clobazam	13 (16.5)
Valproic acid	13 (16.5)
Caregiver's view of intellectual disability, n (%)[d]	
Above average-normal intellect	7 (11.3)
Mild-moderate disability	21 (33.9)
Severe-profound disability	31 (50.0)
Did not state	3 (4.8)
Neuropsychiatric comorbidities, n (%)	
Autism spectrum disorder	47 (59.5)
Anxiety disorder	27 (34.2)
ADHD	21 (26.6)
Other psychiatric disorder(s)	11 (13.9)
OCD	8 (10.1)
Depression	4 (5.1)
Psychotic disorders, including schizophrenia	1 (1.3)

[a]n=37 were adults (≥18 years). [b]Considers participants with any seizure type recorded within 12 months of screening. All participants had a history of seizure(s) but were not necessarily experiencing seizure(s) at the start of the study. The average number of seizures per 28 days at baseline is calculated from seizure diary records. [c]Rescue medication. [d]n=62. ADHD, attention-deficit/hyperactivity disorder; ASMs, antiseizure medications; CBD, cannabidiol; OCD, obsessive-compulsive disorder.

- At the time of this analysis, 79 participants were enrolled; 39 had completed Week 13 and 28 were eligible for Week 26 analysis. 10 participants had discontinued the study
- Median (range) age was 16.0 (3-42) years, and 2.0 (0-6) antiseizure medications were being used at baseline (**Table 2**)
  - The most common concomitant antiseizure medications being used were lamotrigine (n=24 [30%]), midazolam (n=18 [23%]), clobazam (n=13 [17%]), and valproic acid (n=13 [17%])
- Half of the caregivers (50%) characterized their participants as having severe to profound intellectual disability, while a third of them (34%) reported mild to moderate disability
- The majority of participants reported ≥1 neuropsychiatric comorbidity at baseline, most commonly autism spectrum disorder (60%), anxiety disorder (34%), and ADHD (27%)

Figure 3. Change from baseline in Most Problematic Behavior (MPB)

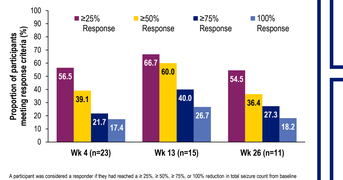


	Baseline[b], median, n=60	Change from baseline at Week 13, median (95% CI)[c], n=29	Change from baseline at Week 26, median (95% CI)[c], n=23
MPB[a] NRS value on TAND-SQ	9.0	−2.0 (−4.0, −1.0)	−2.0 (−3.0,−1.0)

[a]MPB is a novel endpoint uniquely personalized to the patient and defined as the single behavior identified by the caregiver as most troublesome for the participant based on the TAND-SQ checklist. Behaviors are scored 0-10 (0 = not a problem; 10 = extreme problem in the past month). [b]At baseline, prospective participants must have had a MPB score of ≥6 (at least a moderate behavioral problem) on TAND-SQ to be eligible. [c]95% CI for the median change from baseline was calculated using the distribution-free method.
MPB, most problematic behavior; NRS, numerical rating scale; TAND, tuberous sclerosis complex–associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist.

- At baseline (n=60), the median MPB numerical rating scale (NRS) value was 9.0, suggesting severe TAND problems; aggressive outbursts (23%) and anxiety (11%) were the most identified MPBs at baseline
- At Week 26 (n=23), median (95% CI) change from baseline in MPB NRS was −2.0 (−3.0, −1.0), suggesting an improvement in behavioral outcomes from baseline (**Figure 3**)

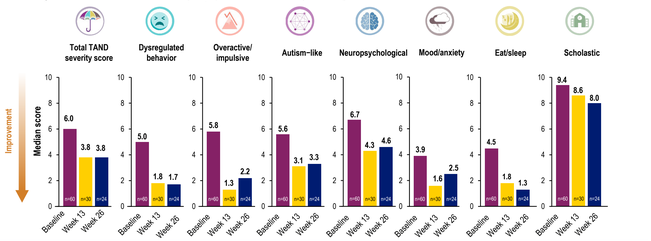
Figure 7. Seizure response from baseline to Week 26



A participant was considered a responder if they had reached a ≥ 25%, ≥ 50%, ≥ 75%, or 100% reduction in total seizure count from baseline during the treatment period. Full analysis set, n=62.
Participants who were not experiencing seizures at baseline were removed; 38/61 at Wk 4, 24/39 at Wk 13, and 14/25 at Wk 26. Wk, week.

- Over half of the participants experiencing seizures at baseline (60%) achieved a ≥50% reduction in total seizure count at Week 13, and more than a third (36%) achieved this threshold at Week 26
- 67% of the participants experiencing seizures at baseline achieved ≥25% reduction in total seizure count from baseline at Week 13, as did 55% at Week 26 (**Figure 7**)

Figure 4. Change from baseline in TAND Self-Report, Quantified Checklist (TAND-SQ)

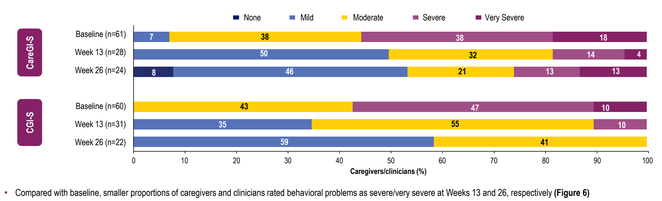


	Baseline, median, n=60	Change from baseline at Week 13, median (95% CI)[a], n=29	Change from baseline at Week 26, median (95% CI)[a], n=23
Total TAND severity score	6.0	−1.4 (−2.0, −0.8)	−1.4 (−2.2, −0.2)
Dysregulated behavior	5.0	−2.0 (−3.0, −0.7)	−0.7 (−2.7, 0.0)
Overactive/impulsive	5.8	−2.0 (−3.0, −0.3)	−1.3 (−3.3, 0.0)
Autism-like	5.6	−1.7 (−2.5, −1.0)	−0.8 (−2.0, 0.0)
Neuropsychological	6.7	−1.4 (−2.7, −0.3)	−0.6 (−3.6, 0.7)
Mood/anxiety	3.9	−1.0 (−2.0, −0.3)	−0.8 (−2.0, 0.0)
Eat/sleep	4.5	−0.5 (−2.0, 0.0)	−2.0 (−3.5, 0.0)
Scholastic	9.4	−0.3 (−1.0, 0.0)	−0.3 (−1.8, 0.0)

[a]95% CI for the median change from baseline was calculated using the distribution-free method. N numbers differ between the graph and table due to the potential for missing data at baseline and/or visits.
CI, confidence interval; TAND, tuberous sclerosis complex–associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist.

- Of the TAND-SQ cluster severity scores, the greatest reduction from baseline to Week 26 (median [95% CI]) was seen in eat/sleep (−2.0 [−3.5, 0.0]) and overactive/impulsive (−1.3 [−3.3, 0.0]) scores (**Figure 4**)

Figure 6. Caregiver (CareGI-S) and Clinician (CGI-S) Global Impression of Severity in problems with behavior



- Compared with baseline, smaller proportions of caregivers and clinicians rated behavioral problems as severe/very severe at Weeks 13 and 26, respectively (**Figure 6**)

Change from baseline in Child Behavior Checklist (CBCL)[a] at Week 26

- At Week 26, improvements in scores from baseline were seen across several problem scales of the CBCL (**Table S1**)
- Among children attending school, the greatest improvement in score was seen in Aggressive Behavior syndrome scale (median [95% CI] −6.0 [−8.0, 3.0])

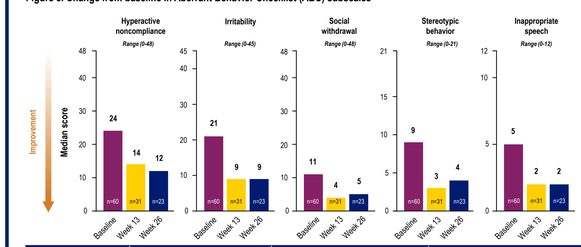
[a]CBCL is used for participants aged between ≥6 and ≤17 years. Higher score is indicative of a greater problem.

Change from baseline in Adult Behavior Checklist (ABCL)[a] at Week 26

- At Week 26, improvements in scores from baseline were observed across most problem scales of the ABCL (**Table S2**)
- Among adults, the greatest improvement in scores were seen in Rule-breaking Behavior (median [95% CI] −3.0 [−6.0, 1.0]) and Other Problems[c] syndrome scale (median [95% CI] −3.0 [−7.0, 2.0])

[a]ABCL is used for participants aged between ≥18 and ≤59 years. Higher score is indicative of a greater problem. [c]Includes clinically-relevant items that don't fit into the other defined syndrome scales such as (but not limited to) sleep disturbances, unusual thought patterns, repetitive behaviors, and emotional dysregulation.

Figure 5. Change from baseline in Aberrant Behavior Checklist (ABC) subscales



	Baseline, median, n=60	Change from baseline at Week 13, median (95% CI)[a], n=30	Change from baseline at Week 26, median (95% CI)[a], n=23
Hyperactive noncompliance	24.0	−9.0 (−16.0, −2.0)	−7.0 (−13.0, −2.0)
Irritability	21.0	−8.5 (−12.0, −4.0)	−8.0 (−10.0,−2.0)
Social withdrawal	11.0	−4.0 (−6.0, −1.0)	−3.0 (−8.0, −1.0)
Stereotypic behavior	9.0	−3.0 (−5.0, −2.0)	−3.0 (−5.0, 0.0)
Inappropriate speech	5.0	−1.0 (−3.0, 0.0)	−2.0 (−3.0, 0.0)

[a]95% CI for the median change from baseline was calculated using the distribution-free method. N numbers differ between the graph and table due to the potential for missing data at baseline and/or visits.
CI, confidence interval.

- Among the ABC subscales, the greatest reduction from baseline to Week 26 was seen in irritability (−8.0 [−10.0, −2.0]) and hyperactive noncompliance (−7.0 [−13.0, −2.0]) scores (**Figure 5**)

Table 3. Safety outcomes

	CBD (N=79)
Participants with ≥1:	**n (%)**
TEAEs	49 (62.0)
Related TEAEs	34 (43.0)
TEAEs leading to CBD discontinuation[a]	11 (13.9)
Serious TEAEs[b]	6 (7.6)
TEAEs occurring in >15% of participants	**n (%)**
Diarrhea	19 (24.1)
Infections	18 (22.8)
Psychiatric disorders	13 (16.5)

[a]Some patients may have had ≥1 TEAEs leading to CBD discontinuation. [b]Serious TEAEs that were considered treatment-related included hypermetremia and seizures (in the same patient), and suicidal ideation and hypokalemia in 1 patient each. 2 out of 3 patients discontinued — 1 due to suicidal ideation and 1 due to hypokalemia (n=1). 1 patient had their CBD dose reduced due to hypermetremia. All events were resolved.
AEs, adverse events; CBD, cannabidiol; TEAEs, treatment-emergent adverse events.

- TEAEs occurred in 49 (62.0%) participants, most commonly diarrhea, infections, and psychiatric disorders (**Table 3**)
- Serious TEAEs were reported in 6 (7.6%) participants; 4 AEs in 3 participants were considered treatment-related (resolved)

Retention

- At the time of this intermediate data analysis, the probability of participants remaining on CBD treatment at Week 26 was 86%; only 1 participant transitioned to SOC after 26 weeks of CBD treatment

Limitations

- This is an intermediate analysis of an open-label study that did not include a control group. Observed improvements may be confounded by potential regression to the mean, particularly given the smaller Week 26 sample size

Conclusions

- In this intermediate analysis, reductions in behavioral outcomes scores as measured on the TAND-SQ, ABC, CBCL, and ABCL were reported after 26 weeks of CBD initiation
- Additionally, reduction in severity of behavioral outcomes as measured on the CareGI-S and CGI-S scales were reported by caregivers and clinicians after 26 weeks
- Safety profile was consistent with previous studies
- Participants currently enrolled in the study are continuing treatment through 52 weeks; final results are expected late in 2026

References: **1.** Vanclooster S, et al. *J Neurodev Disord.* 2022;14(1):13. **2.** de Vries PJ, et al. *J Neurodev Disord.* 2023;15(1):32. **3.** US Food and Drug Administration. Epidiolex® Prescribing Information. 2025. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/210365s023lbl.pdf. (Accessed September 25, 2025.) **4.** Epidyolex® 100 mg/ml oral solution: summary of product characteristics. https://www.ema.europa.eu/en/documents/product-information/epidyolex-epar-product-information_en.pdf. (Accessed October 29, 2025). **5.** van Eeghen AM, et al. Poster presented at TSC International Research Conference, June 26–28, 2025; Bethesda, MD, USA (P.7.) **6.** TAND Consortium. https://tandconsortium.org/about/#tsc. (Accessed October 16, 2025). **7.** Chambers N, et al. *Orphanet J Rare Dis.* 2025;20:304. **8.** Heunis TM, et al. *Pediatr Neurol* 2023;147:101-123. **9.** van Eeghen AM, et al. *PLoS One.* 2025;20(6):e0324648.

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Tuberous Sclerosis Complex (TSC)–Associated Neuropsychiatric Disorders (TAND) Outcomes Following Adjunctive Cannabidiol (CBD) Treatment: 6-Month Intermediate Analysis of the EpiCom Trial

Supplementary Material

Table S1. Change from baseline in Child Behavior Checklist (CBCL) at Week 26

Problem scale	Syndrome scale	Baseline (n=28), median	Week 26 (n=7), median	Change from baseline at Week 26 (n=7), median (95% CI)[a]
Internalizing	Anxious/Depressed	5.0	2.0	−2.0 (−4.0, 5.0)
	Withdrawn/Depressed	3.0	1.0	−1.0 (−4.0, 4.0)
	Somatic Complaints	2.0	2.0	0.0 (−4.0, 3.0)
	Total	**9.5**	**10.0**	**−4.0 (−10.0, 6.0)**
Externalizing	Aggressive Behavior	14.5	10.0	−6.0 (−8.0, 3.0)
	Rule−breaking Behavior	3.0	1.0	−1.0 (−3.0, 2.0)
	Total	**18.0**	**11.0**	**−8.0 (−9.0, 5.0)**
Other	Social Problems	8.0	4.0	−2.0 (−3.0, 4.0)
	Thought Problems	7.0	4.0	1.0 (−4.0, 7.0)
	Attention Problems	11.5	7.0	−2.0 (−6.0, 9.0)
	Other Problems	7.0	7.0	−1.0 (−5.0, 5.0)
	Other Total	**36.0**	**21.0**	**−10.0 (−13.0, 25.0)**
Total	Total	64.5	41.0	−12.0 (−31.0, 35.0)

CBCL is used for participants aged between ≥6 and ≤17 years. Higher score is indicative of a greater problem. [a]95% CI for the median change from baseline is calculated using the distribution-free method. CI, confidence interval.

Table S2. Change from baseline in Adult Behavior Checklist (ABCL) at Week 26

Problem scale	Syndrome scale	Baseline (n=28), median	Week 26 (n=15), median	Change from baseline at Week 26 (n=14), median (95% CI)[a]
Internalizing	Anxious/Depressed	4.5	2.0	−2.0 (−3.0, 2.0)
	Withdrawn	4.5	2.0	−1.0 (−4.0, 0.0)
	Somatic Complaints	2.5	2.0	0.0 (−4.0, 1.0)
	Total	**11.0**	**6.0**	**−4.0 (−5.0, −2.0)**
Externalizing	Aggressive Behavior	11.0	5.0	−2.0 (−5.0, 1.0)
	Rule−breaking Behavior	7.0	2.0	−3.0 (−6.0, 1.0)
	Intrusive	3.0	2.0	−1.0 (−2.0, 0.0)
	Total	**22.0**	**8.0**	**−8.0 (−13.0, 3.0)**
Other	Thought Problems	5.5	3.0	−1.5 (−4.0, 1.0)
	Attention Problems	10.0	10.0	−1.5 (−3.0, 1.0)
	Other Problems[b]	13.0	10.0	−3.0 (−7.0, 2.0)
	Other Total	**29.0**	**21.0**	**−7.0 (−13.0, 3.0)**
Total	Total	68.5	37.0	−15.0 (−28.0, 1.0)

ABCL is used for participants aged between ≥18 and ≤59 years. Higher score is indicative of a greater problem. [a]95% CI for the median change from baseline is calculated using the distribution-free method. [b]Includes clinically relevant items that don't fit into the other defined syndrome scales such as (but not limited to) sleep disturbances, unusual thought patterns, repetitive behaviors, and emotional dysregulation CI, confidence interval.

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