Title Page

SYNOPTIC CLINICAL STUDY REPORT

Study Title:	A randomized, double-blind, placebo-controlled, multisite, Phase 3 study to investigate the efficacy and safety of cannabidiol oral solution (GWP42003-P) in children and adolescents with epilepsy with myoclonic-atonic seizures
Brief Title:	A safety and efficacy study of cannabidiol oral solution (GWP42003-P) in children and adolescents with epilepsy with myoclonic-atonic seizures between 1 and 18 years of age, inclusive.
Study Number:	GWEP20238
Study Phase:	3
Study Intervention:	GWP42003-P (cannabidiol oral solution)
Indication:	Treatment of seizures associated with epilepsy with myoclonic-atonic seizures (EMAS) syndrome in participants between 1 and 18 years of age, inclusive
Brief Description:	A safety and efficacy study of cannabidiol oral solution (GWP42003-P) in children and adolescents with epilepsy with myoclonic-atonic seizures between 1 and 18 years of age, inclusive.
Study Sponsor:	Jazz Pharmaceuticals Inc. on behalf of GW Research Ltd. 3170 Porter Drive, Palo Alto, CA 94304
Study Initiation Date:	21 Mar 2023
Early Study Termination Date:	28 Sep 2023
Regulatory Agency Identifier Number:	EudraCT Number: 2021-003094-61 IND: [redacted]
Report Date:	**Document Version** / **Date** Synoptic CSR Version 1.0 / 04 Mar 2024
This study was conducted in compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP), including the archiving of essential documents.	

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List of Abbreviations and Definitions of Terms

AE	Adverse event
ADR	Adaptive Design Report
ASM	Antiseizure medication
BID	Twice daily
[redacted]	[redacted]
[redacted]	[redacted]
CBD	Cannabidiol
CGIC	Caregiver Global Impression of Change
[redacted]	[redacted]
COVID-19	Coronavirus disease 2019
CSR	Clinical Study Report
C-SSRS	Columbia-Suicide Severity Rating Scale
DS	Dravet syndrome
ECG	12-lead electrocardiogram
eDiary	Electronic diary
EMAS	Epilepsy with myoclonic-atonic seizures
EudraCT	European Union Drug Regulating Authorities Clinical Trials
[redacted]	[redacted]
ICF	Informed consent form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
INR	International normalized ratio
ILAE	International League Against Epilepsy
LGS	Lennox-Gastaut syndrome
OLE	Open-label extension
OS	Oral solution
[redacted]	[redacted]
[redacted]	[redacted]
PGIC	Physician Global Impression of Change
QTL	Quality tolerance limit
RBQM	Risk Based Quality Management
SAE	Serious adverse event
TEAE	Treatment-emergent adverse event

TESC	The Epilepsy Study Consortium
TSC	Tuberous sclerosis complex
USA	United States of America
UK	United Kingdom

Synoptic Report Body

Study Title:

A randomized, double-blind, placebo-controlled, multisite, Phase 3 study to investigate the efficacy and safety of cannabidiol oral solution (GWP42003-P) in children and adolescents with epilepsy with myoclonic-atonic seizures

Study Number:

GWEP20238

Study Phase:

3

Name of Study Intervention:

GWP42003-P (cannabidiol oral solution)

Name of Sponsor/Company:

Jazz Pharmaceuticals Inc. on behalf of GW Research Ltd. 3170 Porter Drive, Palo Alto, CA 94304.

Number of Study Center(s) and Countries:

Participants were to be screened for eligibility to participate in the study at 30 study centers selected for the study in 4 countries (USA, UK, Italy, and Australia). At the time of study termination, 3 patients had been screened at study centers in the USA, of whom 2 had been randomized and 1 was a screen failure. Of the planned 30 study centers, 14 were activated at the time of study termination; 10 sites in the USA and 4 in Italy.

Publications (if any):

Not applicable.

Study Period:

Study Initiation Date: 21 Mar 2023

Early Study Termination Date: 28 Sep 2023

The data presented in this report are based on a database lock date of 13 Nov 2023.

Rationale:

For details, refer to Appendix 8.1/Protocol Amendment 2.0 V4/Section 2.2.

Objectives and Endpoints:

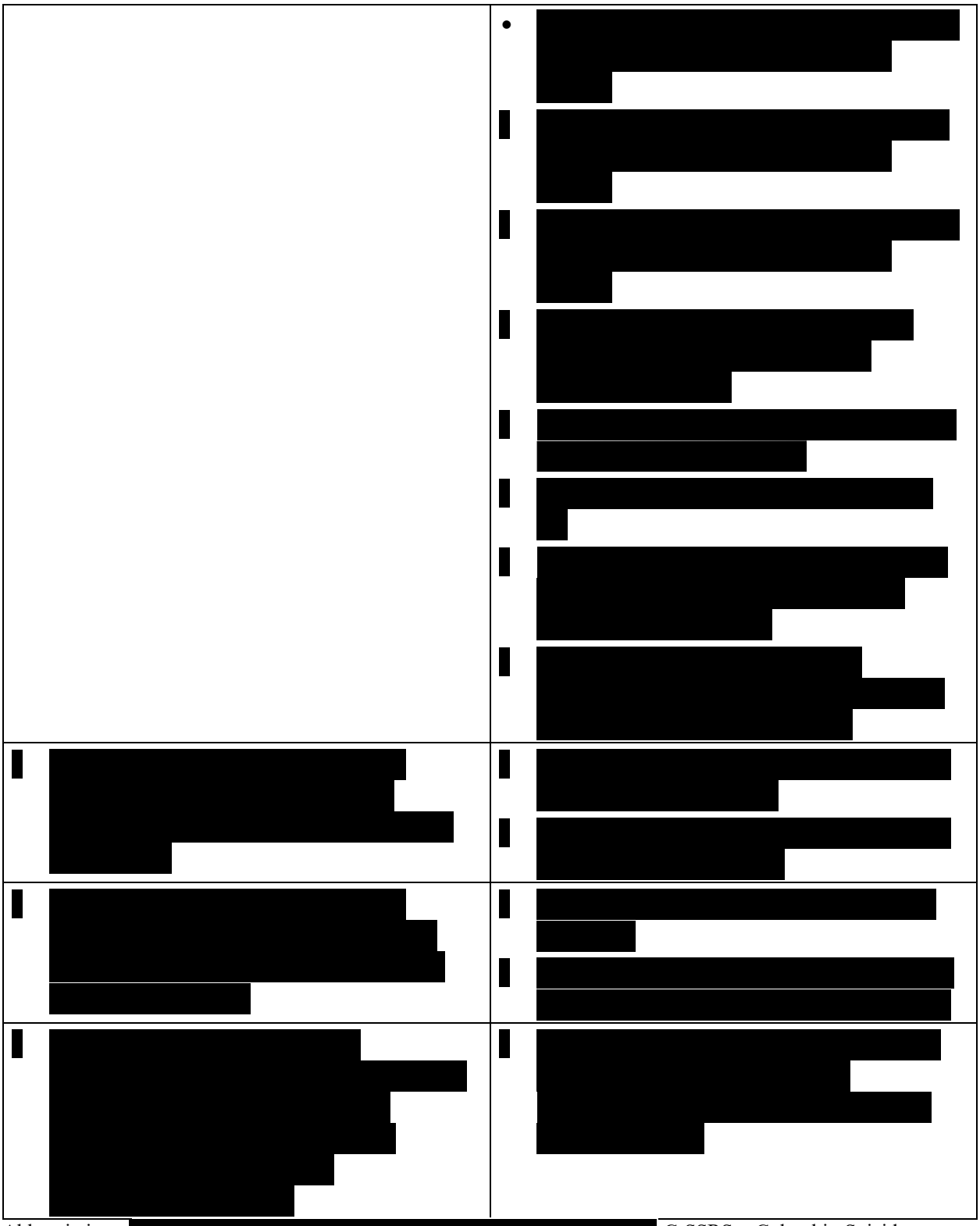
Table 1 and Table 2 list the objectives and endpoints that are described in this report.

Table 1 Study Objectives and Endpoints Part A

Primary	
• To evaluate the efficacy of GWP42003-P compared with placebo in reducing the frequency of EMAS-associated seizures	• Change in EMAS-associated seizure frequency (myoclonic-atonic, atonic, tonic, clonic, or tonic-clonic) during the 14-week treatment period compared to baseline
Key Secondary	
• To evaluate the rate of treatment response to GWP42003-P compared with placebo in reducing the frequency of EMAS-associated seizures	• Proportion of participants who achieve ≥ 50% reduction from baseline in EMAS-associated seizures over the 14-week treatment period
• To evaluate the effect of GWP42003-P compared with placebo on caregiver impression of change	• CGIC score at Week 14
• To evaluate the effect of GWP42003-P in reducing the frequency of all seizure types compared with placebo	• Change in total seizure frequency during the 14-week treatment period compared to baseline
Secondary	
• To evaluate the effect of GWP42003-P compared with placebo on physician impression of change	• PGIC score at Week 14
• To evaluate the effect of GWP42003-P compared with placebo on additional antiepileptic measures from daily seizure diaries	• Proportion of participants who achieve ≥ 25%, ≥ 75%, and 100% reduction from baseline in EMAS-associated seizures over the 14-week treatment period • Proportion of participants who achieve ≥ 25%, ≥ 50%, ≥ 75%, and 100% reduction from baseline in total seizures over the 14-week treatment period • Change from baseline in number of EMAS-associated seizure-free days over the 14-week treatment period • Proportion of participants with ≥ 25% and ≥ 50% reduction in the number of days per week with myoclonic seizures during the treatment period • Time to baseline seizure frequency

• To evaluate the safety and tolerability of GWP42003-P compared with placebo	• Frequency of TEAEs over the 14-week treatment period
	• Laboratory tests
	• Vital signs
	• ECG
	• Tanner Staging
	• Change in:
	  o C-SSRS ideation score
	  o Number of suicide attempts in the C-SSRS

[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]



Abbreviations: C-SSRS = Columbia-Suicide Severity Rating Scale; CBD = Cannabidiol; CGIC = Caregiver Global Impression of Change; ECG = 12-lead electrocardiogram; EMAS = Epilepsy with myoclonic-atonic seizures;

CCI PGIC = Physician Global Impression of Change; TEAE = Treatment-emergent adverse event.

Table 2 Study Objectives and Endpoints Part B

Primary	

• To evaluate the long-term safety and tolerability of GWP42003-P in participants with EMAS	• Frequency of TEAEs over the 48-week treatment period
	• Laboratory tests
	• Vital signs
	• ECG
	• Tanner Staging
	• Change in:
	  ○ C-SSRS ideation score
	  ○ Number of suicide attempts in the C-SSRS

Key Secondary	
• To evaluate long-term effect of GWP42003-P on seizure frequency and additional measures	• Change in EMAS-associated seizure frequency (myoclonic-atonic, atonic, tonic, clonic, or tonic-clonic) compared to baseline • Proportion of participants achieving ≥ 50% reduction in EMAS-associated seizures • CGIC score • Change in total seizure frequency compared to baseline
Secondary	
• To evaluate long-term effect of GWP42003-P on additional measures	• PGIC score • Proportion of participants who achieve ≥ 25%, ≥ 75%, and 100% reduction in EMAS-associated seizures from baseline • Proportion of participants who achieve ≥ 25%, ≥ 50%, ≥ 75%, and 100% reduction in total seizures from baseline • Proportion of participants with ≥ 25% and ≥ 50% reduction in the number of days per week with myoclonic seizures

Abbreviations: C-SSRS = Columbia-Suicide Severity Rating Scale; CGIC = Caregiver Global Impression of Change; ECG = 12-lead electrocardiogram; EMAS = Epilepsy with myoclonic-atonic seizures; PGIC = Physician Global Impression of Change; TEAE = treatment-emergent adverse event.

Statistical Considerations:

Due to a sponsor decision, the study was terminated early due to challenges with recruitment, and no planned analyses occurred.

For Part A, the primary hypothesis to be tested was as follows:

- Following 14 weeks of treatment, the effect of GWP42003-P on EMAS-associated seizure frequency during the treatment period compared to baseline is greater than that in the placebo group, ie, the ratio of the change in EMAS-associated seizure frequency between GWP42003-P and placebo is less than 1.

Based on a consistent treatment effect observed in previous pivotal studies of GWP42003-P in DS, LGS, and TSC, the primary efficacy analysis was to utilize Bayesian methodology to borrow external data from these studies.

The primary endpoint and the key secondary endpoints were to be tested using a hierarchical gatekeeping procedure. The prespecified posterior probability for success of the previous endpoint was to be met to claim superiority based on the prespecified posterior probability for success of the subsequent key secondary endpoint.

No Bayesian analyses or formal hypothesis testing were to be performed for any other endpoints for Part A; analyses of all other endpoints were to be descriptive only.

For Part B (long-term assessment), no statistical hypotheses were planned, and no Bayesian analyses or formal hypothesis testing were to be performed.

For Part A, the study design had an adaptive sample size, in which there was a sample size update (ie, an interim analysis planned) when 60, 75, 90, and 105 participants were randomized. The maximum sample size of this study was 120 randomized participants. The sample size update was to be based on Bayesian methodology to make sample size decisions. At each interim analysis 1 of 3 outcomes was possible: 1) stop enrollment of new participants for expected success, 2) stop the study for futility (nonbinding), or 3) continue enrolling.

The Bayesian primary analysis was to be performed when all randomized participants had the opportunity to complete the 14-week treatment period. Further details on the planned Bayesian primary analysis and interim decisions are described in Appendix 8.1/ Protocol Amendment 2.0 V4/Section 9.4 and 9.5 of the Clinical Study Protocol, respectively, with additional details provided in the ADR.

Virtual study simulations were to be used to determine the operating characteristics (eg, power, Type I error, average sample size) for this study design based on the following assumptions:

- Accrual was to be simulated weekly from a random Poisson process, in which the mean accrual rate was 4 participants per month.
- The accrual pattern included a ramp-up of 6 months to the designated maximum mean rate.
- Mean change in log seizure frequency in the placebo group was -0.28.
- GWP42003-P mean difference from placebo in change in log seizure frequency was -0.396 (a 33% reduction in seizure frequency over placebo).
- Variance of the log change in seizure frequency was 0.388 in the placebo group and 0.962 in the GWP42003-P group.

Based on these assumptions and the borrowing of results from the historical pivotal studies, the study had approximately 90% power to detect a 33% reduction in the log seizure frequency for GWP42003-P versus placebo. In addition, under an assumption of a 33% reduction in log seizure frequency, the probability of concluding superiority early was 0.734 with an average sample size

of 91 participants. Under the null scenario of no treatment benefit, the probability of stopping early for futility is 0.438 with an average sample size of 106 participants.

At the point of early termination, there was a need to unblind the 2 randomized participants to determine the necessary ongoing treatment.

Study Design:

Study GWEP20238 was a multisite, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of GWP42003-P compared to placebo as a treatment for children and adolescents with EMAS, followed by an OLE phase. The study consisted of 2 parts:

Part A (Double-Blind, Randomized, Placebo-Controlled Portion):

The duration of study participation was approximately 26 weeks, which included a 1- to 3-week screening period, 4-week baseline observation period, 14-week dose-optimization treatment period, 10-day taper period, and a safety follow-up period (4 weeks after end-of-taper visit).

After the ICF was signed, participants were screened to enter the study from Day -49 to Day –35 (Visit 1) and commence a 28-day baseline period beginning at Day –28 (Visit 2), before returning for a randomization visit and treatment initiation (Day 1 [Visit 3]).

On Day –28 (Visit 2), participants who continued to meet eligibility criteria were contacted by phone and commenced a 28-day baseline period, before returning for a randomization visit and treatment initiation (Day 1 [Visit 3]).

On Day 1 (Visit 3), participants were randomized centrally in a 1:1 ratio to receive either GWP42003-P or matching placebo. Randomization was stratified by clobazam use (on/off) and age of seizure onset (3 years of age and younger or older than 3 years of age).

Study intervention during the 14-week treatment period followed a flexible titration schedule to enable optimization of dosage.

Part B (Open-Label Extension):

Part B was planned to evaluate the long-term safety, tolerability, and exploratory efficacy of GWP42003-P for a period of 48 weeks in participants with EMAS-associated seizures. The 2 randomized participants only participated in Part A. No participant was able to transition into Part B at the time of study termination.

For details refer to Appendix 8.1/Protocol Amendment 2.0 V4/Section 4.

All changes in the conduct of the study were implemented by protocol amendments (Appendix 8.1).

No modifications of study visits and study procedures were necessary due to the COVID-19 pandemic.

Number of Participants (planned and analyzed):

In Part A, up to a maximum of 120 participants (up to 60 per treatment arm) was planned to be randomly assigned to the study intervention. The final sample size was to be determined by the

planned interim analyses. A total of 2 participants was randomized into the study at the time of study termination on 28 Sep 2023.

Diagnosis and Main Criteria for Inclusion and Exclusion:

Eligibility Criteria:

The key eligibility criteria included:

- Male and female participants between 1 and 18 years of age who had a current diagnosis of EMAS, also known as Doose syndrome, myoclonic-astatic epilepsy, or myoclonic-atonic epilepsy, consistent with the ILAE guidelines;
- Experienced a minimum average frequency of ≥ 2 TESC-approved, countable, EMAS-associated seizures (myoclonic-atonic, atonic, tonic, clonic, or tonic-clonic) per week (≥ 8 seizures per month), as reported in the baseline seizure eDiary from baseline (Part A Visit 2) until the evening prior to randomization (Part A Visit 3);
- Initial seizure onset occurred from ≥ 6 months to < 6 years of age, with normal or mildly impaired/delayed neurodevelopment reported prior to onset of seizures;
- Was currently treated with 1 or more ASMs on a stable regimen (≥ 28 days prior to starting the baseline period [Part A Visit 2]) or on a stable ketogenic diet/epilepsy dietary therapy (≥ 28 days prior to starting the baseline period [Part A Visit 2]);
- Had failed ≥ 1 prior ASM due to inadequate seizure control.

Detailed inclusion and exclusion criteria are provided in Appendix 8.1/Protocol V4/Section 5.1 and Section 5.2.

Table 3 Study Interventions, Dose, Mode of Administration, and Batch Number(s):

Arm Name	GWP42003-P	Placebo
Intervention Name	GWP42003-P	Placebo
Type	Drug	Drug
Dose Formulation	CBD dissolved in the excipients sesame oil and anhydrous ethanol (10% v/v), with sweetener (sucralose), and strawberry flavoring	The excipients sesame oil and anhydrous ethanol (10% v/v), with sweetener (sucralose), strawberry flavoring, and beta carotene
Unit Dose Strength(s)	100 mg/mL CBD	n/a
Dosage Level(s)	5 mg/kg/day (2.5 mg/kg BID) up to a maximum of 20 mg/kg/day	0.05 mL/kg/day up to a maximum of 0.2 mL/kg/day
Batch Number[a]	111029, 112895, 113459, 114677	112050, 113944
Route of Administration	Oral	Oral
Use	Experimental	Placebo comparator
Study intervention or non-study intervention	Study intervention	Study intervention
Sourcing	Provided centrally by the sponsor	Provided centrally by the sponsor

Packaging and Labeling	The study intervention will be provided in bottles with syringes for administration. Each bottle will be labeled as required per country requirement.	The study intervention will be provided in bottles with syringes for administration. Each bottle will be labeled as required per country requirement.
Current/Former Names or Alias	Cannabidiol	N/A

Abbreviations: BID = twice daily; CBD = cannabidiol; N/A = not applicable; v/v = volume/volume.
[a] The batch numbers indicated were packed and shipped to the depots; however, as the study enrolled only 2 participants, not all of the batch numbers were used for the participants.

Duration of Study Intervention:

In Part A, participants were to receive oral doses of 5 mg/kg/day (2.5 mg/kg BID) up to a maximum of 20 mg/kg/day.

The duration of study participation was planned to be approximately 26 weeks, which included a 1- to 3-week screening period, 4-week baseline observation period, 14-week dose optimization treatment period, 10-day taper period, and a safety follow-up period (4 weeks after end of taper visit).

In Part B, participants were planned to receive oral doses of 5 mg/kg/day (2.5 mg/kg BID) up to a maximum of 20 mg/kg/day.

The duration of study for Part B was planned to be approximately 54 weeks, which included a 48-week treatment period (including a 2-week blinded titration [or transition] period for all participants), 10-day taper period, and a safety follow-up period (4 weeks after end-of-taper visit).

Risk Based Quality Management

An RBQM approach, aligned with ICH E6 (R2) Section 5.0, was followed throughout this study. Critical data and processes with the potential to impact participant protection and/or the reliability of study results were identified, and associated risks were defined and evaluated. Critical and high priority risks were mitigated where possible by measures such as adjusting protocol design, training, defined study processes, planning contingencies, and risk monitoring. Risk monitoring included the use of key risk indicators. Signals from risk monitoring were followed up to eliminate, or minimize, the impact on participant protection and the reliability of study results. RBQM activities and reviews were documented in the study risk register.

There were no significant deviations from predefined QTLs during this study.

Summary of Results and Conclusions:

Disposition, Demographic and Other Baseline Characteristics:

A total of 3 participants was enrolled into Part A of the study, with 2 undergoing randomization. One participant received GWP42003-P and 1 participant received placebo (Listing 10.1.2.1). No participants entered Part B of the study (Listing 10.1.2.1).

Disposition and study discontinuation information and protocol deviations are provided in Listing 10.1.2.1, Listing 10.1.2.2, and Listing 10.2, respectively.

Additionally, the description of the single screen failure and reason for screen failure are provided in Listing 10.1.1 and Listing 10.1.3, respectively.

Demographics and baseline characteristics for the Part A Safety Analysis Set are provided in Listing 10.4.1. The Part A Safety Analysis Set comprised 1 male and 1 female. The age of these participants was 3 and 4 years old, respectively (Listing 10.4.1).

Detailed listings of medical history included in the Part A Safety Analysis Set are provided in Listing 10.4.1, Listing 10.4.2, Listing 10.4.3, and Listing 10.5.

Prior and concomitant medications for the Part A Safety Analysis Set are provided in Listing 10.6.1 and Listing 10.6.2.

Exposure:

One participant began GWP42003-P dosing at 0.4 ml BID and at study termination the participant received 1.6 ml BID. The other participant began placebo dosing at 0.6 ml BID and at study termination the participant received 2.5 ml BID. Exposure data are provided in Listing 10.9.1 and Listing 10.9.2.

Efficacy Results:

Not applicable.

Pharmacokinetic Results:

Not applicable.

Safety Results:

Overall, both participants experienced at least 1 AE and both participants experienced AEs that were considered to be related to the study intervention (Listing 10.10.1).

Treatment-Related/Treatment-Emergent Adverse Events:

Overall, TEAEs were reported by both participants.

The 1 participant in the GWP42003-P treatment group experienced TEAEs of fatigue and irritability, which were considered related to study intervention, and TEAEs of gastroenteritis viral, tachycardia, and INR increased that were considered unrelated to study intervention. The participant in the placebo group experienced a TEAE of irritability that was considered related to the study intervention and a TEAE of blood triglycerides increased that was considered unrelated to study intervention (Listing 10.10.1).

Serious Treatment-Emergent Adverse Events:

The 1 participant in the GWP42003-P treatment arm experienced the SAE of viral gastroenteritis that was considered severe. The SAE resolved without treatment and was not considered related to the study intervention. No SAEs were reported for the placebo treatment arm (Listing 10.10.1).

Fatal TEAEs and TEAEs Leading to Discontinuation:
No AEs were fatal or led to the discontinuation of study intervention.

TEAEs of Special Interest:

Not applicable.

Summary of Clinical Laboratory Findings:

There were no clinically meaningful trends observed in clinical laboratory results. The participant receiving GWP42003-P experienced an INR of 1.49 on Day 27, which was reported as a nonserious TEAE. No action was taken, and the event was assessed as not related to study intervention by the investigator. Individual laboratory results are provided in Listing 10.11.

Summary of Vital Signs, ECGs, and C-SSRS assessments:

There were no vital sign parameters (including pulse rate, pulse oximetry, respiratory rate, and temperature), ECG, or suicidality assessments that were reported as AEs. There were also no clinically meaningful findings in the vital sign parameters, or the ECG and C-SSRS data (Listing 10.12.2 and Listing 10.12.3, respectively). Individual vital signs results are provided in Listing 10.12.1.

Summary of Data Safety Monitoring Committee Review

Not applicable.

Conclusions:

No conclusions regarding the efficacy and safety of GWP42003-P can be made from the limited data from Study GWEP20238. Only 2 participants were randomized into the study (1 participant was randomized to GWP42003-P and 1 participant was randomized to placebo) at the time the decision was made to terminate the study due to challenges with recruitment.

Date and Version of This Report:

GWEP20238 Synoptic CSR, Version 1.0, 04 Mar 2023.

8. STUDY INFORMATION

8.1. Study Protocol, Protocol Amendments, and Summary of Changes

8.1.1. GWEP20238 Original Clinical Protocol

8.1.2. GWEP20238 Clinical Protocol Amendment 01 United Kingdom

8.1.3. GWEP20238 Clinical Protocol Amendment 1.1 Italy

8.1.4. GWEP20238 Clinical Protocol Amendment 02

8.2. Sample Case Report Forms

8.2.1. Sample Case Report Form

8.3. Sample Consent Forms and Written Participant Information

8.3.1. GWEP20238 Informed Consent Form Assent (12-17 years) V1.0

8.3.2. GWEP20238 Informed Consent Form Assent (5-11 years) V2.0

8.3.3. GWEP20238 Informed Consent Form Parental and Adult V2.0

8.4. List of Investigators, Ethics Committees, and Other Important Participants

8.4.1. List of Investigators, Ethics Committees, and Other Important Participants

8.5. Signatures

8.5.1. Internal Signatures

8.5.2. External Signatures

8.6. List of Participants Receiving Test Drug from Specific Batches

8.6.1. List of Participants Receiving Test Drug from Specific Batches

8.7. Audit Certificates

8.7.1. Clinical Trial Audit Certificate

8.8. Documentation of Statistical Methods

8.8.1. Statistical Analysis Plan

8.8.2. Adaptive Design Report

8.9. Documentation of Laboratory Methods and Quality Assurance Procedures – Not Applicable

8.10. Publications – Not Applicable

8.11. Additional Reports – Not Applicable

9. DATA TABLES, FIGURES AND GRAPHS

9.1. Demographics

Not applicable.

9.2. Efficacy

Not applicable.

9.3. Safety

Not applicable.

10. DATA LISTINGS

10.1. Discontinued Participants

- Listing 10.1.1 Screen Failures (All Screen Failure Participants)
- Listing 10.1.2.1 Participant Disposition – End of Treatment (Part A Safety Analysis Set)
- Listing 10.1.2.2 Participant Disposition – Treatment Discontinuation (Part A Safety Analysis Set)
- Listing 10.1.3 Inclusion/Exclusion Criteria Not Met (All Screened Patients)

10.2. Protocol Deviations

- Listing 10.2 All Protocol Deviations (All Screened Patients)

10.3. Participants Excluded From the Efficacy Analysis – Not Applicable

10.4. Demographic Data

- Listing 10.3.1 Demographics (Part A Safety Analysis Set)
- Listing 10.4.1 History of Current Seizures (Part A Safety Analysis Set)
- Listing 10.4.2 Neuroimaging History (Part A Safety Analysis Set)
- Listing 10.4.3 EEG History (Part A Safety Analysis Set)
- Listing 10.5 Significant Non-Epilepsy Medical or Surgical History (Part A Safety Analysis Set)
- Listing 10.6.1 Concomitant Anti-Seizure Maintenance and Rescue Medications and Therapies (Part A Safety Analysis Set)
- Listing 10.6.2 Other Concomitant Medications (Part A Safety Analysis Set)
- Listing 10.6.3 Other Procedures and Non-Drug Therapies (Part A Safety Analysis Set)

10.5. Compliance and/or Drug Concentration Data

- Listing 10.7.1.1 eDiary Data – Seizure eDiary (Part A Safety Analysis Set)
- Listing 10.7.1.2 eDiary Data – Reminder Seizure eDiary (Part A Safety Analysis Set)
- Listing 10.7.1.3 eDiary Data – Morning and Evening Dosing eDiaries (Part A Safety Analysis Set)
- Listing 10.7.1.4 eDiary Data – Food eDiary (Part A Safety Analysis Set)
- Listing 10.8.1 Subject/Caregiver/Physician Global Study Impression of Change (Part A Safety Analysis Set)

- Listing 10.8.2 Subject/Caregiver Global Impression of Change in Seizure Duration (Part A Safety Analysis Set)
- [redacted]
- Listing 10.8.4 Achenbach Child Behavior Checklist (Part A Safety Analysis Set)
- Listing 10.8.5 Behavior Rating Inventory of Executive Functioning (Part A Safety Analysis Set)
- Listing 10.8.6 Treatment Credibility/Expectancy Questionnaire – Parent Version (Part A Safety Analysis Set)
- Listing 10.9.1 Exposure and Compliance (Part A Safety Analysis Set)
- Listing 10.9.2 IMP Accountability (Part A Safety Analysis Set)

10.6. Individual Efficacy Response Data

Not applicable.

10.7. Adverse Events

- Listing 10.10.1 Adverse Events (Part A Safety Analysis Set)

10.8. Individual Laboratory Measurements by Participant

- Listing 10.11 Laboratory Parameters (Part A Safety Analysis Set)
- Listing 10.12.1 Vital Signs (Part A Safety Analysis Set)
- Listing 10.12.2 ECG Data (Part A Safety Analysis Set)

10.9. Other Listings

10.9.1. Other Safety Data

- Listing 10.12.3 Columbia-Suicide Severity Rating Scale (C-SSRS) (Part A Safety Analysis Set)
- Listing 10.12.7.1 Plasma Concentrations of CBD, 7-OH-CBD and 7-COOH-CBD (Part A Safety Analysis Set)
- Listing 10.12.7.2 Meal Times (Part A Safety Analysis Set)

11. NARRATIVES

11.1. Deaths

- Not applicable

11.2. Serious Adverse Events

- Participant 1608-001

11.3. Withdrawals Due to Adverse Events

- Not applicable.

11.4. Other Clinically Significant Events

- Not applicable.

12. COMPLETED CASE REPORT FORMS

Completed Case Report Forms are provided for participants with a narrative.