Statistical Analysis Plan

Protocol No.: GV1001-PSP-CL2-011

A Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel design, Prospective, Phase IIa Exploratory Clinical Trial to evaluate the efficacy and safety of Subcutaneous Administration of GV1001 0.56 or 1.12 mg/day in Patients with Progressive Supranuclear Palsy

Sponsor: GemVax&KAEL

Author: [redacted]

Protocol Version: GV1001-PSP-CL2-011_Version 5.1, 2024-03-15

SAP Version: SAP_GV1001-PSP-CL2-011_Version 1.0, 2024-10-10

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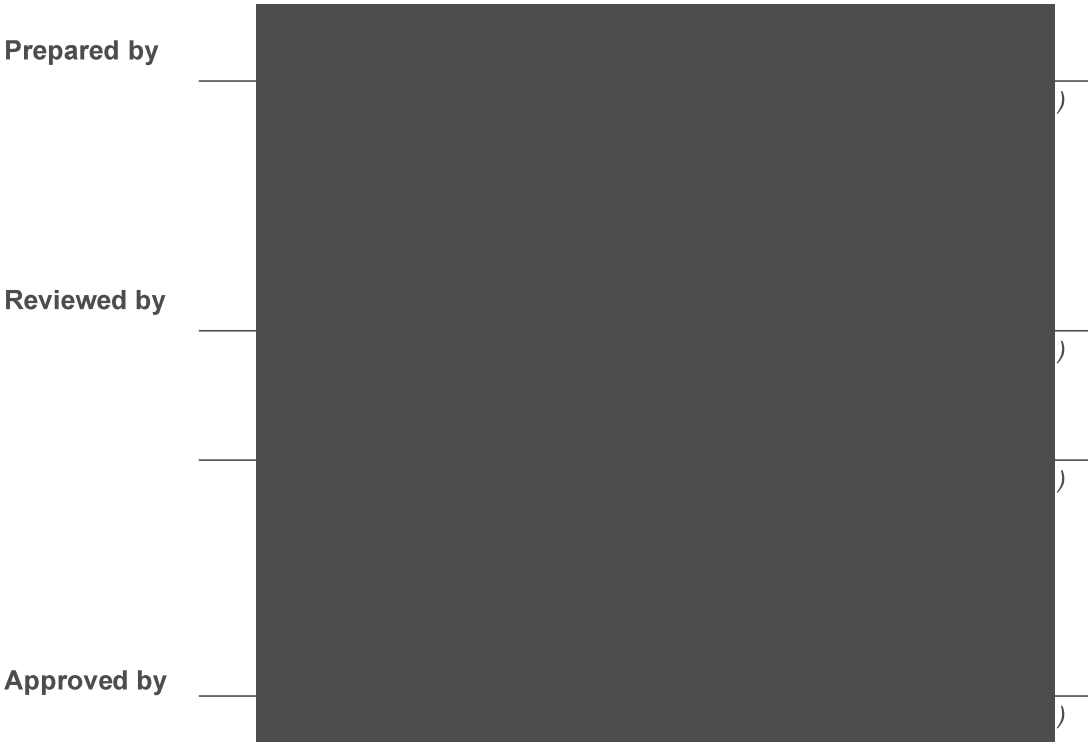

History of Revision

Original Version	Amendment Version	Approval Date	Reason
Version 1.0		2024-10-10	Newly Created

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Term	Definition
ADR	Adverse Drug Reaction
AE	Adverse Event
CS	Clinically Significant
eCRF	Electronic Case Report Form
EOS	End of Study
EOT	End of Treatment
ES ADL	England & Schwab Activity Of Daily Living
FAS	Full Analysis Set
FSH	Follicle Stimulating Hormone
hCG	human Chorionic Gonadotropin
IP	Investigational Product
K-FAB	Korean Frontal Assessment Battery
K-MMSE	Korean Mini-Mental State Examination
LSM	Least Squares Mean
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	Mixed-Effect Model Repeated Measure
MoCA-K	Montreal Cognitive Assessment-Korean Version
NCS	Not Clinically Significant
PPS	Per-Protocol Set
PSP	Progressive Supranuclear Palsy
PSP-p	Progressive Supranuclear Palsy-parkinsonism
PSP-RS	Progressive Supranuclear Palsy-Richardson's Syndrome
PT	Preferred Term
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event

2. INTRODUCTION

This document describes the statistical analysis plan for protocol GV1001-PSP-CL2-011. The details of the data processing and analysis methods used for statistical analysis have been described, and demographic information, efficacy and safety data will be summarized and analyzed according to the methods in this statistical analysis plan.

3. SUMMARY OF KEY PROTOCOL INFORMATION

3.1 Study Objective

3.1.1 Primary Objective

To explore the efficacy and evaluate the safety of GV1001 0.56 mg/day or 1.12 mg/day administered for 24 weeks on the severity of disease in patients with progressive supranuclear palsy.

3.1.2 Secondary Objective

To collect source data to determine the possibility of progression to the next stage of development and to subsequent clinical studies by analyzing the clinical and biological parameters associated with the treatment response and safety information of 2 dose levels of GV1001, 0.56 mg/day or 1.12 mg/day, in patients with progressive supranuclear palsy.

3.2 Study Design

This is a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel design, prospective, Phase 2a exploratory clinical study.

If the subject and/or the subject's representative provide a written consent to participate in this clinical study, the required examinations and tests will be performed at the screening visit, and the screening period will run for 4 weeks or shorter.

Subjects who are ultimately determined as eligible by the inclusion/exclusion criteria after screening will be randomized at a 1:1:1 ratio to Study Group 1 (GV1001 0.56 mg/day), Study Group 2 (GV1001 1.12 mg/day), or the placebo group depending on the study site in which they are enrolled. Depending on the randomization results, subjects will be administered the investigational product (study drug or placebo) once weekly for the first 4 weeks (1 month), and then administered 10 times at 2-week intervals for 20 weeks (5 months) for a total of 14 doses over 24 weeks (6 months).

All subjects will visit the study site according to the planned clinical study schedule to receive the investigational product and to be evaluated for efficacy and safety. To ensure the objectivity and accuracy of the study results, the efficacy evaluators evaluating the PSP-rating scale will be limited to neurologists who have been sufficiently educated and trained, and the collection of efficacy and safety evaluation data and biomarkers will be performed in a consistent order at each visit.

※ Neurological drugs administered at a stable dose for at least 1 month prior to a subject's participation in this clinical study (prior to screening) will be continued without changing the dose during the clinical study participation period.

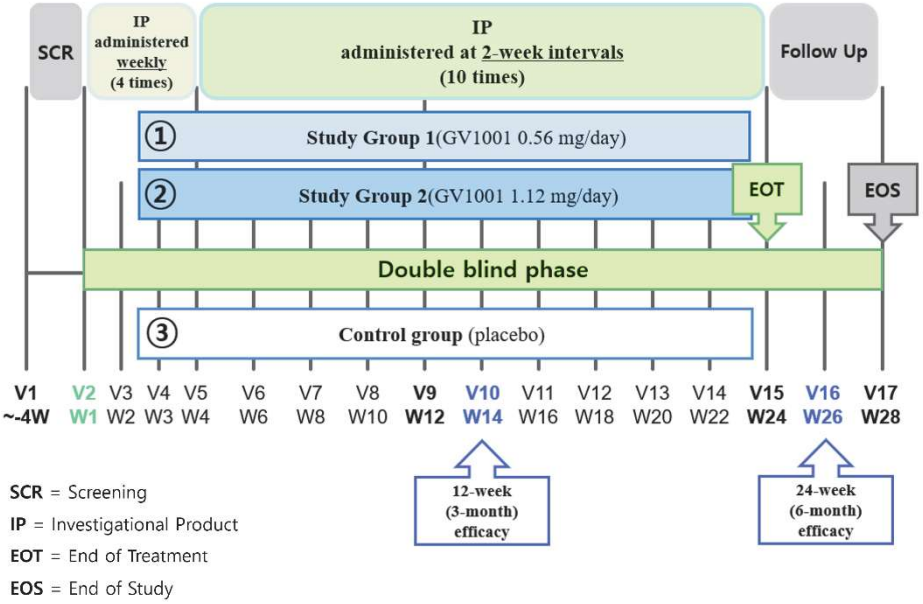

Figure. Clinical Study Schematic

3.3 Determination of the Sample Size

Total number of subjects: 75 subjects (75 subjects in total with 25 subjects per group considering a dropout rate of 20%)

	Study Group 1	Study Group 2	Control Group	Total Number of Subjects
Number of Subjects	20	20	20	60
Number of Subjects Considering Dropout (20%)	25	25	25	75

This is a Phase 2a exploratory clinical study conducted for the purposes of collecting initial safety and efficacy information on the investigational product GV1001 in patients with progressive supranuclear palsy as well as providing the basis for design, evaluation items, and evaluation methods for subsequent clinical studies. Since this is a study to estimate the clinically significant effect size to demonstrate the efficacy of this investigational product, the number of subjects was not calculated based on statistical considerations. The minimum number of subjects required in a pilot study is 12 subjects[2)] and approximately 30 subjects can be considered according to the rule of thumb[3), 4)]. Therefore, by combining these, it is intended to set 20 subjects per group, and a total of 75 subjects with 25 subjects per group will be enrolled considering a dropout rate of 20%.

3.4 Schedule of Study

Period	Screening	Double blind treatment phase													Follow Up	
Week	~ -4	1	2	3	4	6	8	10	12	14	16	18	20	22	24	26	28
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 EOT	16	☎ 17 EOS
Visit window (days)	-	-	±3			±5										±5	±5
Subject Consent and Assignment of Screening Number	○																
Demographic Information	○																
Checking Medical/Surgical History	○	○															
Checking prior/concomitant medications	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Physical examination	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Vital signs	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Weight	○	○				○				○						○	
Height	○																
Electrocardiography[1]	○									○						○	
Laboratory tests[2]	○	○				○				○						○	
Urine hCG[3]	○	○				○		○		○		○		○		○	
Checking inclusion/exclusion criteria	○	○															

Period		Screening	Double blind treatment phase														Follow Up	
Week		~ -4	1	2	3	4	6	8	10	12	14	16	18	20	22	24	26	28
Visit		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 EOT	16	☎ 17 EOS
Visit window (days)		-	-	±3			±5										±5	±5
Randomization			○															
K-MMSE[4]		○																
PSP-rating scale		○									○						○	
MoCA-K			○								○						○	
K-FAB			○								○						○	
ES ADL			○								○						○	
Brain CT[5]		(○)																
Collecting human-derived samples[6]	DNA, Plasma, Serum	○									○						○	
	Cerebrospinal fluid	○															○	
Investigational product administration[7]			○	○	○	○	○	○	○	○	○	○	○	○	○	○		
Adverse Event Assessment[8]			○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

[1] Electrocardiography: For the Visit 1 (screening) test, the results of a test performed within 3 months may be used if available, and retesting may be performed only once at the discretion of the investigator.
[2] Laboratory tests: For the Visit 1 (screening) tests, the results of tests performed within 4 weeks may be used if available, and retesting may be performed only once at the discretion of the investigator. At Visit 1 (screening), the serum FSH tests shall be performed to confirm menopause in women aged ≥41 years to <55 years who have experienced amenorrhea for more than 1 year.
· Hematology test: WBC, RBC, Hemoglobin, Hematocrit, Platelets count, WBC differential count (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils)
· Blood chemistry test: BUN, Creatinine, Uric acid, Total bilirubin, Albumin, Total Protein, ALT, AST, γ-GTP, Alkaline phosphatase, Glucose, Total Cholesterol, HbA1c (performed only at screening visit)

· Serum Follicle Stimulating Hormone test: FSH (Performed only at screening visit for those who require confirmation of menopause)
· Urinalysis: Protein (Albumin), Glucose, Ketones, WBC, Blood (RBC)
· Blood coagulation test: INR (performed only at screening visit)
· Thyroid test: TSH, free T4 (performed only at screening visit)
· Syphilis, AIDS tests: VDRL or RPR, anti-HIV (performed only at screening visit)
· Serum creatinine clearance will be confirmed using the Cockcroft-Gault formula. (performed only at screening visit)
CLcr = [(140 − Age (years)] × Weight (kg) × 0.85 (for female subjects) / 72×Serum Creatinine (mg/dl)
[3] Urine hCG: Urine hCG pregnancy tests will be performed only for women of childbearing potential, excluding subjects confirmed to have undergone surgical sterilization and as being menopausal. However, for Visit 1 (screening), the subjects who performed the serum FSH test to confirm menopause when participating in the clinical study will also perform urine hCG pregnancy test.
[4] K-MMSE: The results of a test performed at the study site within 2 weeks prior to the screening visit may be used if available.
[5] Brain CT: This will be performed only on subjects without brain CT imaging within 12 months prior to the screening visit.
[6] Collecting human-derived samples: Human-derived samples (DNA, plasma, serum, and cerebrospinal fluid) will be collected for exploratory evaluations, and they will be transferred to the central lab for analysis and storage. However, in the case of cerebrospinal fluid, it will be collected only from subjects who have separately consented to collection of samples. For Visit 1 (screening), separate visits for collecting human-derived samples can be set up and implemented within the screening period.
[7] Investigational product administration: Subjects will be observed for approximately 20 minutes after the administration of the investigational product from Visit 2 to Visit 15.
[8] Adverse events assessment: Adverse events that occurred after the first administration of the investigational product will be identified, and prior to the first administration, it will be collected as medical history.

3.5 Changes to Analysis from Protocol

Protocol Language	SAP Language Changed from Protocol	Reason of Change
none	9.2.7 Change from the baseline in the total score of modified PSP-rating scale 10 after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration (…)	Add extra secondary efficacy endpoint for further exploration of efficacy
none	9.2.8 Change from the baseline in the total score of modified PSP-rating scale 14 after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration (…)	Add extra secondary efficacy endpoint for further exploration of efficacy
none	9.2.9 Proportion of subjects with change from the baseline in the total score of PSP-rating scale ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type] (…)	Add extra secondary efficacy endpoint for further exploration of efficacy
none	9.2.10 Proportion of subjects with change from the baseline in the total score of Modified PSP-rating scale 10 ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type] (…)	Add extra secondary efficacy endpoint for further exploration of efficacy
none	9.2.11 Proportion of subjects with change from the baseline in the total score of Modified PSP-rating scale 14 ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type] (…)	Add extra secondary efficacy endpoint for further exploration of efficacy
11.2.6. Subgroup Analysis Subgroup analysis will not be considered in this clinical study.	11. SUBGROUP ANALYSES Subgroup analyses for efficacy will be conducted on the endpoint related with PSP-rating scale, modified PSP-rating scale 10 and modified PSP-rating scale 14 for FAS using the same analysis methods (refer to 9.1 and 9.2). **Subgroup Variable** / **Category** PSP Type / • Richardson type [PSP-RS] • Parkinsonian type [PSP-p]	Add subgroup analysis for further exploration of efficacy

4. PLANNED ANALYSIS

4.1 Interim Analysis

No interim analysis will be performed before the end of the clinical study. However, an interim analysis related to the safety of this clinical study may be conducted when a serious issue related to safety is discovered and the need is recognized through a meeting or a deliberation of the investigator or principal investigator.

4.2 Final Analysis

The planned final analysis is performed after sequentially completing the following steps.

1. All subjects in the study will complete the visit defined in the protocol (LPO, Last Patient Out) and all data problems will be resolved through query.
2. The database is locked after the analysis set definition is confirmed via blind meeting and email communication.
3. Unblinding process will be conducted.

5. GENERAL CONSIDERATIONS FOR SUMMARIES AND ANALYSES

5.1 Significance Level

Unless otherwise specified, all statistical tests will be two-sided hypothesis tests performed at the 5% level of significance and all confidence intervals will be two-sided 95% confidence intervals.

5.2 Statistical Analysis Methods

For continuous data, the normality test will determine the parametric or nonparametric methods by the p-value of Shapiro-Wilk test (reference to section 14.1) with the 5% level of significance. Unless otherwise specified, the two-sample t-test (if normality assumption is satisfied) or Wilcoxon's rank-sum test (if normality assumption is not satisfied) will be used to compare each study group with the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group). For a within-group comparison, the paired t-test if the assumption of normality is satisfied or Wilcoxon's signed rank test if the assumption of normality is not satisfied, will be used.

For a between-group comparison of categorical data, a chi-square test will be basically used and when more than 20% of the table cells have expected frequencies that are less than 5, Fisher's exact test will be presented. A between-group comparison will be used to compare each study group with the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group). For confidence intervals of proportion of categorical data, if more than 20% of the table cells in the contingency tables for between-group comparison have expected frequencies that are less than 5, then exact two-sided 95% confidence intervals (Clopper-Pearson) will be calculated.

5.3 Stratifications

Not Planned

5.4 General Reporting Conventions

5.4.1 Summary Statistics

- Continuous data: Summary statistics will be presented with the number of subject(n), mean, standard deviation (SD), median, minimum (min), and maximum (max).

- Categorical data: Summary statistics will be presented with frequencies (n) and percent (%).
- When the statistics or p-value etc. are not calculated, It is presented as '-'.

5.4.2 Decimals

- Decimal place and presented down to 2nd decimal place.
- Categorical data: Percentage will be rounded up from the 3rd decimal place and presented down to 2nd decimal place.
- P-value

  - P-values will be reported to 4th decimal place.

  - If the calculated p-value is below 0.0001, it will be presented as '<0.0001'.
- Vital signs, ECG and laboratory test

  Results for vital signs and ECG will be showed 1 more digit from maximum decimal places for each item, and results for clinical laboratory tests will be showed 1 more digit from maximum decimal places of the standard unit conversion value for each item.

  For example, in laboratory tests, if the longest decimal place of original unit's measured value is 2 decimal places and conversion factor is 1 decimal place (i.e. the longest decimal place of standard unit's measured value is 3 decimal places), the statistic is rounded off from the 5 decimal places to 4 decimal places.

5.5 Reference Start Date and Study Day

The study day of an event is defined as the relative day of event starting from the date of randomization (reference date, Visit 2). The study day to an event cannot be 0.

- The study day of events occurring before the randomization will be calculated as:
  Study Day (days) = (Date of event – Date of Randomization)
- The study day of events occurring on or after the first randomization will be calculated as:
  Study Day (days) = (Date of event – Date of Randomization) + 1

Study days will only be calculated for events with completed start dates and will not be calculated for events if the start date of event is not completed.

5.6 Baseline Definition

Unless otherwise specified, Baseline is defined as the last observed value without missing prior to the first IP administration.

5.7 Medical Dictionary and Version

The Medical Coding Name and Version applied to this study are as follows.

- Medical History and Adverse Events: Medical Dictionary for Regulatory Activities (MedDRA) 26.1 or latest version
- Prior Medication/Concomitant Medication: WHODrug Global 2023 or latest version

5.8 Software Version

SAS® (version 9.4 or higher, Enterprise BI Server, SAS institute Inc., Cary, NC, USA).

6. DATA HANDLING CONVENTIONS

6.1 Handling of Missing Data

When analyzing the efficacy endpoints and exploratory endpoints, in the case of utilizing the mixed-effect model repeated measure (MMRM) method, the available data will be analyzed as they are since the method does not require the replacement of missing values. If missing values occur in the safety endpoints and exploratory endpoints analyzed by methods other than MMRM, analysis will be performed only on the collected data without imputation.

In the PSP-rating scale, if an item has no response, the available items with responses will be used to calculate the total score and the score for each domain. The calculated scores will be converted to the same scale as the total score and the score for each domain if all items are not missing. In modified PSP-rating scale, if there is a non-response for each item, the total score and the corresponding score for each domain will be considered as missing.

6.2 Windowing Conventions

The results of efficacy assessments performed after randomization in this study will include not only regular visits, but also early termination/withdrawal visits and unscheduled visits, and measurements from the visit within the visit window will be used for the analysis.

Visit	Actual Point	Visit Window	Analysis Window Valid Relative Range*
Visit 1 (Screening)	~ - 4 Week	-	
Visit 2 (Baseline)	Week 1	-	1
Visit 3	Week 2	± 3 Days	5~11 days
Visit 4	Week 3	± 3 Days	12~18 days
Visit 5	Week 4	± 3 Days	19~25 days
Visit 6	Week 6	± 5 Days	31~41 days
Visit 7	Week 8	± 5 Days	45~55 days
Visit 8	Week 10	± 5 Days	59~69 days

Visit	Actual Point	Visit Window	Analysis Window Valid Relative Range*
Visit 9	Week 12	± 5 Days	73~83 days
Visit 10	Week 14	± 5 Days	87~97 days
Visit 11	Week 16	± 5 Days	101~111 days
Visit 12	Week 18	± 5 Days	115~125 days
Visit 13	Week 20	± 5 Days	129~139 days
Visit 14	Week 22	± 5 Days	143~153 days
Visit 15 (EOT)	Week 24	± 5 Days	157~167 days
Visit 16	Week 26	± 5 Days	171~181 days
Visit 17 (EOS)	Week 28	± 5 Days	185~195 days

* If a violation of the drug administration schedule occurs, the analysis window will be modified as the process in the protocol 5.5.2.

6.3 Early Termination and Withdrawal Assessments

Data collected from early termination/withdrawal visits apply to the analysis as follows.

- Efficacy endpoints
  - In accordance with section 6.2, analysis is performed as result of a regular visit only when it comes within the visit window corresponding to each regular visit.
- Safety endpoints
  - It is excluded from the analysis of regular visits but will be presented in the listing.
  - If early termination/withdrawal visit is the last visit, the result value will be summarized as final visit.

6.4 Repeated or Unscheduled Assessments

In accordance with section 5.6, if there is more than one result prior to the first IP administration, the latest result before the first IP administration will be considered as a baseline.

In case there are measurements from an unscheduled visit after the first dose of IP, measurements at scheduled and unscheduled visit are chronologically presented in the subject list whereas summary of descriptive statistic by time point will only include measurements at scheduled visits. If two or more data within same visit window exist, the value from regular visit will be used for analysis.

6.5 Handling of Incomplete Dates

For AE data, in case day or month is omitted from the start date, only collected date units will be used without any imputation of date. When the entire start date is missing or the format of the collected AE date does not allow for comparison, the AE will be assumed to be TEAE.

For medication, in case day or month is omitted from the start or end date thus collected as 'UK', only collected date units will be used without any imputation of date. When the entire start date is missing or the format of the collected start date does not allow for comparison with the first IP administration date, the medication is assumed to being used prior to the first dose administration date of the investigational product.

6.6 Character Values of Clinical Laboratory Variables

In summary of laboratory data, minimum or maximum value will be used if value includes inequality sign (ex. use 4 for '≥4 or >4' and use 100 for '≤100 or <100'). When listing the results for subjects, the values recorded in eCRF (such as value with inequality sign) will be presented.

7. ANALYSIS SETS

The main analysis of efficacy evaluation of this clinical study will be performed on the full analysis set (FAS) and the analysis on the per-protocol set (PPS) will be performed as a supplement. The safety evaluation analysis will be performed as actually administered in the safety set. The exploratory evaluation analysis will be performed on the FAS and PPS, and the demographic and the characteristics prior to administration will be analyzed for Randomized Set.

7.1 Screened Set

The screened set is defined as subjects who sign the informed consent form and are assigned a screening number.

7.2 Randomized Set

Randomized set consists of data from all subjects who are randomized into the study.

7.3 Full Analysis Set (FAS)

This includes subjects who received at least 1 dose of the investigational product after randomization and had at least 1 evaluation with the PSP-rating scale after the administration of the investigational product and up to the end of the clinical study. In the FAS, subjects will be included in the group to which they were randomized.

7.4 Per-Protocol Set (PPS)

Among the subjects included in FAS, the subjects who completed the clinical study without major protocol violations are included. Subjects with major protocol violations (see 5.5.3 Protocol Violations section in the protocol) may be excluded from PPS.

Exclusion from PPS will be decided through a blind meeting prior to database lock, after comprehensively discussing whether the clinical study was affected.

7.5 Safety Set

Among the subjects who were administered at least one dose of the investigational product after randomization, subjects whose safety-related data were evaluated at least once after the administration will be included.

8. STUDY POPULATION ANALYSES

8.1 Subject Disposition

The disposition of all screened subjects will be summarized for overall subject (total) and by treatment group.

For the screened set, the number of screened subjects, screened failed subjects, and the reasons for screening failure will be summarized by overall subject. For the Randomized set, the number of subjects who are randomized and the number and percentage (%) of subjects who are treated/not treated and completed/early termination will be summarized by treatment group and overall subject. The number of the reasons for discontinuation also will be presented by treatment group and overall subjects. Subject disposition will be presented as a summary table and a figure. Also, screening failed subjects and discontinued subjects will be listed.

8.2 Important Protocol Deviations

For the Randomized set, important protocol deviations will be summarized as the number of subjects, percentage (%), and the number of events by treatment group and overall. Also, important protocol deviation data will be listed.

8.3 Analysis Set

For all subjects in Randomized set, Subjects in each analysis set (Safety set, FAS and PPS) will be summarized with counts and percent for overall subject and by treatment group. The reason excluded from each analysis set will be summarized with count for overall subject and by treatment group. Subjects exclude from each analysis set will be listed.

8.4 Demographic

8.4.1 Variable, Definition and/or Derivation

Demographic will be presented by treatment group.

Variables	Unit or Categories
Age	Years
Age group	• < 65 years • ≥ 65 years
Derivation Method: eCRF [Demographics] page에 기재된 Age를 기준으로 실제 연령 그룹으로 분류	
Sex	• Male • Female
Baseline BMI	kg/m^2

Variables	Unit or Categories
Derivation Method: Baseline Body Weight (kg) / (Baseline Height (cm) x 0.01)^2	
Fertility	• Yes • No • Perform serum FSH test
Menopause	• Yes • No
Duration of PSP	months
Derivation Method: (Randomization Date – Diagnosis Date + 1) x 12 / 365.25 - If day or month is omitted from the first date of diagnosis, will be using "01" imputation of date. If year is omitted from the first date of diagnosis, the subject will be excluded from the analysis.	
PSP Type	• Richardson type [PSP-RS] • Parkinsonian type [PSP-p]

8.4.2 Method of Analysis

For the Randomized Set, Demographics will be summarized using descriptive statistics by treatment group and overall subject (total). Continuous variables will present the number of subjects observed, mean, standard deviation, median, minimum, and maximum. In addition, depending on whether the assumption of normality is satisfied, the two-sample t-test (if normality assumption is satisfied) or Wilcoxon's rank-sum test (if normality assumption is not satisfied) will be used to compare each study group with the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group). Categorical variables will present frequencies and percentages, and depending on whether cells with an expected frequency less than 5 exceed 20% of the total cells, Pearson's chi-square test (if the cells with an expected frequency less than 5 does not exceed 20% of the total cells) or Fisher's exact test (if the cells with an expected frequency less than 5 exceed 20% of the total cells) will be used to compare each study group with the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group).

For the Randomized Set, demographics and baseline characteristics data will be listed.

8.5 Medical History and Concurrent Disease

8.5.1 Variable, Definition and/or Derivation

All medical histories will be classified as medical history and concurrent disease according to the following criteria.

Variables	Definition and/or Derivation
Medical History	Maintenance='No' on the [Medical/Surgical History] page of eCRF.
Concurrent Disease	Maintenance='Yes' on the [Medical/Surgical History] page of eCRF.

8.5.2 Method of Analysis

All medical histories will be classified as medical history and concurrent disease and summarized by treatment group and overall subjects in the Randomized Set. The number and percentage (%) of subjects and the number of cases will be presented based on Preferred Term (PT) and System Organ Class (SOC).

Medical/surgical history and concurrent disease will be listed for Randomized set.

8.6 Prior and Concomitant Medication

8.6.1 Variable, Definition and/or Derivation

All medications will be classified as prior and concomitant medication/therapies according to the following criteria.

Variables	Definition and/or Derivation
Prior Medication	- The end date is prior to the date of the first IP administration (The end date < the date of the first IP administration)
Concomitant Medication	- The start date is on or after the date of the first IP administration and on or before the date of End of Study; or (The date of the first IP administration ≤ the start date ≤ the date of End of Study) - The start date is on or before the date of the first IP administration, but the end date is on or after the date of the first IP administration; or (The start date ≤ the date of the first IP administration, and -the end date ≥ the date of the first IP administration) - The end date is ongoing. ('ongoing' is checked on [Prior/Concomitant Medications] page of eCRF)

If the start or end date is missing or incomplete and the prior/concomitant medications cannot be distinguished, they will be classified as concomitant medications.

8.6.2 Method of Analysis

All medications will be classified as prior and concomitant medications and summarized by treatment group in the Randomized Set. The number and percentage (%) of subjects and the number of cases will be presented based on 'Anatomical main group (level 1)', 'Therapeutic subgroup (level 2)' for overall subject and by treatment group.

Prior and concomitant medication will be listed for Randomized Set.

8.7 Drug Compliance

8.7.1 Variable, Definition and/or Derivation

Variables(unit)	Definition and/or Derivation
Drug compliance (%)	$\frac{\text{Actual number of doses administered (injections)}}{\text{Number of doses that should be administered (injections)}} \times 100$ Number of doses that should be administered (injections) = (i) 14, if the subject completes the study (ii) Number of planned injections before discontinuations

8.7.2 Method of Analysis

For the Randomized Set, drug compliance will be summarized using descriptive statistics (the number of subjects, mean, standard deviation, median, minimum and maximum) by treatment group and overall subject (total).

Drug compliance data will be listed for Safety Set.

9. EFFICACY ANALYSES

9.1 Primary Efficacy Endpoint(s)

9.1.1 Variable, Definition and/or Derivation

Change from the baseline in the total score of PSP-rating scale after 24 weeks (6 months)

- Change from baseline at week 24 = week 24 – baseline

9.1.2 Method of Analysis

Descriptive statistics (number of subjects observed, mean, standard deviation, median, minimum, and maximum) will be presented by treatment group for each visit and the change from the baseline in the total score of the PSP-rating scale after 24 weeks (6 months) of investigational product administration. To test the difference between each study group and the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group), an MMRM analysis will be conducted with the treatment groups, visits, and interactions between the visits and the treatment groups set as fixed effects, and the subjects set as the random effect, as well as considering the baseline values, age, and sex as covariates. The results of the MMRM analysis will be summarized by LSM and standard error (SE) for each treatment group, the LSM difference between the study groups and the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group) and its 95% confidence interval as well as the two-side p-value.

Additionally, testing the difference within each treatment group will be conducted by the same MMRM analysis.

MMRM constructed as follows

- Dependent Variable: Change from baseline in total score of PSP-rating
- Fixed Effects

  Fixed Continuous Effects: Baseline PSP-rating, Age

  Fixed Categorical Effects: Treatment, Visit, Visit*Treatment, Sex
- Repeated Effect: Visit
- Random Effect: Subject
- Covariance Structure: Unstructured (UN)

[redacted]

9.1.3 Interpret the Result

The Superiority of each study group to placebo is confirmed when the p-value for the interaction effect at 24 weeks is below 0.05.

9.2 Secondary Efficacy Endpoint(s)

1) Change from the baseline in the total score of PSP-rating scale after 12 weeks (3 months) of investigational product administration
2) Change from the baseline in the Montreal Cognitive Assessment - Korea (MoCA-K) after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
3) Change from the baseline in the Korean Frontal Assessment Battery (K-FAB) after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
4) Change from the baseline in the England & Schwab Activity of Daily Living (ES ADL) scale after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
5) Change from the baseline in the score of each domain of the PSP-rating scale after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
6) Change from the baseline in the score of each item of the PSP-rating scale after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
7) Change from the baseline in the total score of modified PSP-rating scale 10 after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
8) Change from the baseline in the total score of modified PSP-rating scale 14 after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration
9) Proportion of subjects with change from the baseline in the total score of PSP-rating scale ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type]
10) Proportion of subjects with change from the baseline in the total score of Modified PSP-rating scale 10 ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type]
11) Proportion of subjects with change from the baseline in the total score of Modified PSP-rating scale 14 ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type]

9.2.1 Change from the baseline in the total score of PSP-rating scale after 12 weeks (3 months) of investigational product administration

9.2.1.1 Variable, Definition and/or Derivation

- Change from baseline at week 12 = week 12 – baseline

9.2.1.2 Method of Analysis

Descriptive statistics (number of subjects observed, mean, standard deviation, median, minimum, and maximum) will be presented by treatment group for each visit and the change from the baseline in the total score of the PSP-rating scale after 12 weeks (3 months) of investigational product administration. To test the difference between each study group and

the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group), an MMRM analysis will be conducted with the treatment groups, visits, and interactions between the visits and the treatment groups set as fixed effects, and the subjects set as the random effect, as well as considering the baseline values, age, and sex as covariates. The results of the MMRM analysis will be summarized by LSM and standard error (SE) for each treatment group, the LSM difference between treatment groups and its 95% confidence interval, and the two-sided p-value.

Additionally, testing the difference within each treatment group will be conducted by the same MMRM analysis.

MMRM constructed as follows

- Dependent Variable: Change from baseline in total score of PSP-rating
- Fixed Effects

  Fixed Continuous Effects: Baseline PSP-rating, Age

  Fixed Categorical Effects: Treatment, Visit, Visit*Treatment, Sex
- Repeated Effect: Visit
- Random Effect: Subject
- Covariance Structure: Unstructured (UN)

9.2.2 Change from the baseline in the Montreal Cognitive Assessment - Korea (MoCA-K) after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.2.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

9.2.2.2 Method of Analysis

Descriptive statistics (number of subjects observed, mean, standard deviation, median, minimum, and maximum) will be presented by treatment group for each visit and the change from the baseline in MoCA-K after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration. To test the difference between each study group and the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group), an MMRM analysis will be conducted with the treatment groups, visits, and interactions between the visits and the treatment groups set as fixed effects, and the subjects set as the random effect, as well as considering the baseline values, age, and sex as covariates. The results of the MMRM analysis will be summarized by LSM and standard error (SE) for each treatment group, the LSM difference between treatment groups and its 95% confidence interval, and the two-sided p-value.

Additionally, testing the difference within each treatment group will be conducted by the same

MMRM analysis.

MMRM constructed as follows

- Dependent Variable: Change from baseline in MoCA-K
- Fixed Effects

  Fixed Continuous Effects: Baseline MoCA-K, Age

  Fixed Categorical Effects: Treatment, Visit, Visit*Treatment, Sex
- Repeated Effect: Visit
- Random Effect: Subject
- Covariance Structure: Unstructured (UN)

9.2.3 Change from the baseline in the Korean Frontal Assessment Battery (K-FAB) after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.3.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

9.2.3.2 Method of Analysis

Refer to section 9.2.2.2.

9.2.4 Change from the baseline in the England & Schwab Activity of Daily Living (ES ADL) scale after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.4.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

9.2.4.2 Method of Analysis

Refer to section 9.2.2.2.

9.2.5 Change from the baseline in the score of each domain of the PSP-rating

scale after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.5.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

9.2.5.2 Method of Analysis

Refer to section 9.2.2.2.

9.2.6 Change from the baseline in the score of each item of the PSP-rating scale after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.6.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

9.2.6.2 Method of Analysis

Refer to section 9.2.2.2.

9.2.7 Change from the baseline in the total score of modified PSP-rating scale 10 after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.7.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

  See Appendix 2 for calculation of the total score of modified PSP-rating scale 10.

9.2.7.2 Method of Analysis

Refer to section 9.2.2.2.

9.2.8 Change from the baseline in the total score of modified PSP-rating scale 14 after 12 weeks (3 months) and 24 weeks (6 months) of investigational product administration

9.2.8.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=12, 24

  See Appendix 2 for calculation of the total score of modified PSP-rating scale 14.

9.2.8.2 Method of Analysis

Refer to section 9.2.2.2.

9.2.9 Proportion of subjects with change from the baseline in the total score of PSP-rating scale ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type]

9.2.9.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=24
- Proportion of subjects with change ≤ 0 = the number of subjects with change ≤ 0 / the number of subjects with non-missing values x 100

9.2.9.2 Method of Analysis

Proportion of subjects with change from the baseline in the total score of PSP-rating scale ≤ 0 after 24 weeks and its two-sided 95% confidence interval will be provided by treatment group. To compare the study group and control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group), p-value for the differences between groups will be provided using Pearson's chi-square test (if the cells with an expected frequency less than 5 does not exceed 20% of the total cells) or Fisher's exact test (if the cells with an expected frequency less than 5 exceed 20% of the total cells).

9.2.10 Proportion of subjects with change from the baseline in the total score of Modified PSP-rating scale 10 ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type]

9.2.10.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=24
- Proportion of subjects with change ≤ 0 = the number of subjects with change ≤ 0 / the number of subjects with non-missing values x 100

9.2.10.2 Method of Analysis

Refer to section 9.2.9.2.

9.2.11 Proportion of subjects with change from the baseline in the total score of Modified PSP-rating scale 14 ≤ 0 after 24 weeks (6 months) of investigational product administration [Subgroup: Richardson type]

9.2.11.1 Variable, Definition and/or Derivation

- Change from baseline at week n = week n – baseline, n=24
- Proportion of subjects with change ≤ 0 = the number of subjects with change ≤ 0 / the number of subjects with non-missing values x 100

9.2.11.2 Method of Analysis

Refer to section 9.2.9.2.

9.3 Exploratory Evaluation Endpoint(s)

1) Change from the baseline in total tau (t-tau), phosphorylated tau (p-tau), and neurofilament light chain (NfL) markers in blood after 12 weeks (3 months), and in blood and cerebrospinal fluid after 24 weeks (6 months) of investigational product administration
2) Change from the baseline in inflammatory cytokine markers (IL-6, IL-8, IL-2, IFN- γ, TNF-α, etc.) in blood after 12 weeks (3 months), and in blood and cerebrospinal fluid after 24 weeks (6 months) of investigational product administration
3) Change from the baseline in blood after 12 weeks (3 months), and in blood and cerebrospinal fluid markers after 24 weeks (6 months) of investigational product administration, and correlation between clinical markers and treatment responses

9.3.1 Change from the baseline in total tau (t-tau), phosphorylated tau (p-tau), and neurofilament light chain (NfL) markers in blood after 12 weeks (3 months), and in blood and cerebrospinal fluid after 24 weeks (6 months) of investigational product administration

9.3.1.1 Variable, Definition and/or Derivation

- pTau181, pTau217, pTau231, Total tau, NfL
- Change from baseline at week n = week n – baseline, n=12, 24

9.3.1.2 Method of Analysis

Refer to section 9.2.2.2.

9.3.2 Change from the baseline in inflammatory cytokine markers (IL-6, IL-8, IL-2, IFN- γ, TNF-α, etc.) in blood after 12 weeks (3 months), and in blood and cerebrospinal fluid after 24 weeks (6 months) of investigational product administration

9.3.2.1 Variable, Definition and/or Derivation

- IL-6, IL-8, IL-2, IFN-γ, TNF-α, GFAP, UCH-L1
- Change from baseline at week n = week n – baseline, n=12, 24

9.3.2.2 Method of Analysis

Refer to section 9.2.2.2.

9.3.3 Change from the baseline in blood after 12 weeks (3 months), and in blood and cerebrospinal fluid markers after 24 weeks (6 months) of

investigational product administration, and correlation between clinical markers and treatment responses

9.3.3.1 Variable, Definition and/or Derivation

- pTau181, Total tau, NfL, IL-6, IL-8, IL-2, IFN-γ, TNF-α, GFAP, UCH-L1
- Change from baseline at week n = week n – baseline, n=12, 24

9.3.3.2 Method of Analysis

To determine the association of each biomarker with each treatment response, a correlation coefficient is calculated for the 12 weeks and 24 weeks change from baseline for each treatment group. The correlation coefficient is calculated using Pearson's correlation coefficient or Spearman's correlation coefficient, depending on the normality of the data.

10. SAFETY ANALYSES

10.1 Extent of Exposure

10.1.1 Variable, Definition and/or Derivation

Variables	Definition and/or Derivation
Treatment Duration (days)	Date of last IP administration – Date of first IP administration + (additional time exposed)* *additional time exposed = 1, if the subject completes V15 = Minimum(6, Discontinuation date – Date of last administration) + 1, discontinued before V4 = Minimum(13, Discontinuation date – Date of last administration) + 1, discontinued after V4

10.1.2 Method of Analysis

To assess the treatment exposure, descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum) will be presented for treatment duration (days) by treatment group and total.

Exposure data will be listed for Safety Set.

10.2 Adverse Events

10.2.1 Variable, Definition and/or Derivation

Variables	Definition and/or Derivation
Adverse event (AE)	This refers to any harmful and unintended signs (including abnormal laboratory test results, etc.), symptoms, or diseases that occur in a subject who has been administered an investigational product, and it does not necessarily must have a causal relationship to the investigational product.
Treatment-Emergent Adverse Events (TEAEs)	A TEAE is defined as an AE not present before exposure to study drug or any event already present that worsens in severity or frequency after exposure to study drug.
Adverse drug reaction (ADR)	This refers to any harmful and unintended reactions that occur at any dose of an investigational product and of which the causal relationship to the investigational product cannot be denied. TEAE will be considered to be ADR if the causality is evaluated as certain, probable/likely, possible, conditional/unclassified, or unassessable/unclassifiable.
Serious adverse event/adverse drug reaction (serious AE/ADR)	This refers to an adverse event or adverse drug reaction that occurs at any dose of an investigational product that corresponds to any one of the following: ① Occurrence of death or life-threatening risks ② Requires hospitalization or prolongation of hospitalization

Variables	Definition and/or Derivation
	③ Results in permanent or significant disability or functional decline ④ Occurrence of malformations or abnormalities in a fetus ⑤ Other than cases ① through ④, occurrence of drug dependence or abuse, or cases in which medically significant situations occur, such as hematopathies However, in this clinical study, a visit made for the following reasons will not be considered as a serious adverse event. • Hospitalization planned prior to the clinical study • Hospitalization for medical examination, cosmetic reasons, and recuperation • Cases in which the time of visiting the emergency room has not exceeded 24 hours. However, it may be considered a serious adverse event based on the investigator's judgment even if it does not exceed 24 hours. If a situation occurs that is considered to have a significant impact on the patient's well-being and health status, even if not listed above, it shall be determined whether to consider it as a serious adverse event according to the medical judgment of the doctor in charge and relevant specialists, and appropriate measures shall be taken accordingly.

10.2.2 Method of Analysis

10.2.2.1 Overall Summary of Adverse Events

The number of subjects, incidence (%) with its two-sided 95% confidence interval and number of events will be presented for AEs, adverse drug reactions (ADRs), serious adverse events (SAEs), serious adverse drug reactions (SADRs), AEs leading to permanent discontinuation, and AEs leading to death by treatment group. The chi-square test or Fisher's exact test will be used for comparison of AE incidence between GV1001 and Placebo.

Also, Number of events for AEs/ADRs will be presented according to severity, causality to IP, and outcome.

10.2.2.2 Display of Adverse Events

All AEs and ADRs will be presented according to SOC and PT. The following conventions will be used in summarizing AEs:

- For subject incidence summaries, a subject will be counted only once within each SOC and within each PT.
- Summaries by severity – if a subject reports more than 1 AE within an SOC and/or PT, the AE will the highest severity within each SOC and within each PT will be included.

- When the number of events is calculated, more than 1 AE counted as different events

Subjects with TEAEs will be listed for Safety Set.

10.2.2.3 Death and Serious Adverse Events and Other Significant Adverse Events

For SAEs, AEs leading to permanent discontinuation, and AEs leading to death, separate listings and summaries of subject counts and percent together with the number of events will be presented by treatment group and by SOC and PT.

10.3 Clinical Laboratory Analyses

10.3.1 Variable, Definition and/or Derivation

Laboratory Tests*	Variables
Hematology test, Blood chemistry test	Change from baseline at week n = result at week n – result at baseline n=6, 14, 26
	Change from baseline at final visit result at final visit* – result at baseline *the last visit among regular visit, unscheduled visit and End visit/Drop out visit.
Hematology test, Blood chemistry test, Urinalysis test	Normality - Normal - Abnormal NCS - Abnormal CS
	Shift from baseline to week n, n=6, 14, 26 - Normal or Abnormal NCS - Abnormal CS
	Shift from baseline to final visit - Normal or Abnormal NCS - Abnormal CS

* The laboratory tests will include following test items.

Laboratory Test	Laboratory Test Items(unit)
Hematology test	- WBC (10^3/μL) - RBC (10^6/μL) - Hemoglobin (g/dL) - Hematocrit (%) - Platelet count (10^3/μL) - Neutrophils (%) - Lymphocytes (%) - Monocytes (%) - Eosinophils (%) - Basophils (%)
Blood chemistry test	- BUN (mg/dL) - Creatinine (mg/dL) - Uric acid (mg/dL)

Laboratory Test	Laboratory Test Items(unit)
	- Total bilirubin (mg/dL) - Albumin (g/dL) - Total protein (g/dL) - ALT(IU/L) - AST(IU/L) - γ-GTP(IU/L) - Alkaline phosphatase (IU/L) - Glucose (mg/dL) - Total cholesterol (mg/dL)
Urinalysis test	- Protein (Albumin) - Glucose - Ketones - WBC - Blood (RBC)

10.3.2 Method of Analysis

Actual values and changes from baseline for continuous clinical laboratory test results will be summarized by treatment group at each time point using descriptive statistics (number of subjects observed, mean, standard deviation, median, minimum, and maximum). In addition, depending on whether the assumption of normality is satisfied, the intragroup comparison will use the paired t-test or Wilcoxon's signed-rank test, while the intergroup comparison (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group) will use the two-sample t-test or Wilcoxon's rank-sum test to perform analysis.

For categorical variables, shift tables from baseline visit to each scheduled post-baseline visit, will be generated for clinical laboratory test results using Normal or Abnormal not clinically significant (NCS)/Abnormal clinically significant (CS), by treatment group and overall subjects. The intragroup comparison will use McNemar's test, while the intergroup comparison (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group) will use Pearson's chi-square test or Fisher's exact test to perform analysis.

Subjects with normal or abnormal NCS values at baseline that shifted to abnormal CS after baseline on laboratory test will be listed.

10.4 Other Safety Analyses

10.4.1 Vital Signs

10.4.1.1 Variable, Definition and/or Derivation

- Systolic blood pressure (mmHg), Diastolic blood pressure (mmHg), Pulse rate (beats/minute), Respiratory rate (breaths/minute), Body temperature (℃), Body weight (kg)
- Change from baseline at week n = Result at week n – Result at baseline, n = 2, 3, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26 (except body weight), n = 6, 14, 26 (body weight)
- Change from baseline at final visit*= Result at final visit* – Result at baseline

  * the last visit among regular visit, unscheduled visit and End visit/Drop out visit.

10.4.1.2 Method of Analysis

For vital signs, the measurement values at each visit as well as descriptive statistics (number of subjects observed, mean, standard deviation, median, minimum, and maximum) for the changes from the baseline will be presented by treatment group. In addition, to test the intragroup difference before and after investigational product administration, the paired t-test (if normality assumption is satisfied) or Wilcoxon's signed-rank test (if normality assumption is not satisfied) will be performed depending on whether the assumption of normality is satisfied. To test the difference between the study groups and the control group (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group) for the changes from the baseline, the two-sample t-test (if normality assumption is satisfied) or Wilcoxon's rank-sum test (if normality assumption is not satisfied) will be performed depending on whether the assumption of normality is satisfied.

10.4.2 Electrocardiogram

10.4.2.1 Variable, Definition and/or Derivation

Electrocardiogram	Variables
Overall interpretation	Normality - Normal - Abnormal NCS - Abnormal CS
	Shift from baseline to week n, n=14, 26 - Normal or Abnormal NCS - Abnormal CS
	Shift from baseline to final visit - Normal or Abnormal NCS - Abnormal CS

10.4.2.2 Method of Analysis

For electrocardiography, the frequency and percentage by treatment group will be presented using the shift table for the changes in "normal or abnormal NCS" / "abnormal CS" before and after administration. In addition, the intragroup comparison will use McNemar's test, while the intergroup comparison (GV1001 0.56 mg/day vs. control group, GV1001 1.12 mg/day vs. control group) will use Pearson's chi-square test or Fisher's test to perform analysis.

Subjects with normal or abnormal NCS values at baseline that shifted to abnormal CS after baseline on electrocardiogram will be listed.

10.4.3 Physical Examination

10.4.3.1 Variable, Definition and/or Derivation

- Organ systems of physical examination: appearance, skin, head/neck, chest/lungs, heart, abdomen, urinary/genital system, extremities, musculoskeletal system, nervous system, and lymph nodes

10.4.3.2 Method of Analysis

Clinically significant result of physical examination will be listed.

11. SUBGROUP ANALYSES

Subgroup analyses for efficacy will be conducted on the endpoint related with PSP-rating scale, modified PSP-rating scale 10 and modified PSP-rating scale 14 for FAS using the same analysis methods (refer to 9.1 and 9.2).

Subgroup Variable	Category
PSP Type	• Richardson type [PSP-RS] • Parkinsonian type [PSP-p]

12. SENSITIVITY ANALYSES

Sensitivity analysis will not be considered in this clinical study.

13. ADDITIONAL ANALYSES

Additional analysis will not be considered in this clinical study.

14. SAS PROCEDURE FOR TESTING

14.1 Normality Test

14.2 Test for Within Treatment Group Comparison

14.3 Test of Continuous Variable for Between Treatment Groups

14.4 Test of Categorical Variable for Between Treatment Groups

14.5 Test of Correlation Coefficient

15. REFERENCES

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Appendix.

1. Mock-up Tables, Figures and Listings
2. modified PSP-rating scale calculations