This is ACTG A5394 SAP Version 3.0 with names of authors, names of publication writing team members and analysis timeline redacted.

A5394

Primary Statistical Analysis Plan

Version 3.0

July 24, 2026

Safety, Tolerability, and Impact of Oral TLR8 Agonist Selgantolimod on HBsAg in Participants with Both Chronic Hepatitis B and HIV

ClinicalTrials.gov Identifier: NCT05551273

Protocol Version 2.0, dated September 27, 2023

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Version History

Version	Changes Made	Date Finalized
1.0	Original Version	October 4, 2021
1.1	Protocol Version 1.0 review	July 14, 2022
2.0	Protocol Version 2.0 review. • Three Secondary Objectives (previously 9, 10 and11) have been removed in Section 2.3.2. They are Exploratory Objectives in the updated protocol. Related Outcome Measures were removed in Section 3.2. • HBV genotype and HBV diagnosis time were added to Baseline Characteristics in Section 7. • Updated the statistician assignment and Core Writing Team Roster.	December 6, 2023
3.0	Corrections made to the confidence interval alpha in the lab-based analyses to match the protocol.	July 24, 2026

1 Introduction

1.1 Purpose

This Primary Statistical Analysis Plan (SAP) describes the primary estimands, key secondary estimands, and other secondary outcome measures that will address specific study objectives and interim monitoring of the A5394 study. The Primary SAP includes general analytic approaches for all primary estimands, key secondary estimands, and other outcome measures in the primary manuscript(s) or submitted to ClinicalTrials.gov. The Primary SAP facilitates discussion of the statistical analysis components among the lead study investigators and statisticians, helping them agree on the statistical analyses to be performed and presented in the primary analysis report.

A separate SAP will provide outlines of analyses for other objectives and outcome measures not included in the Primary SAP.

1.2 Version History

- Version 1.0: Not applicable; original version.
- Version 1.1: No changes after review of Protocol Version 1.0 dated May 27, 2022.
- Version 2.0: Changes are based on review of Protocol Version 2.0, dated September 27, 2023.
    - Three Secondary Objectives (previously 9, 10 and 11) have been removed in Section 2.3.2 because they are now listed as Exploratory Objectives in the updated protocol. Related Outcome Measures were removed in Section 3.2.
    - HBV genotype and HBV diagnosis time were added to Baseline Characteristics in Section 7.
    - Updated statistician assignment and Core Writing Team Roster.
- Corrected typos in specifying alpha in the confidence intervals for the lab-based analyses, to match the protocol. Corrections are bolded in Section 5.1.3. and 5.2.1.

2 Study Overview

2.1 Overview of Study Design

A5394 is a phase II, double-blinded, placebo-controlled trial. The study aims to assess safety and decline in qHBsAg with the administration of oral toll-like receptor (TLR) 8 agonist selgantolimod (SLGN) in people with chronic HBV (CHB) and HIV-1, who have been receiving effective antiviral therapy for HIV (ART) and HBV for ≥5 years and have qHBsAg level >1000 (3 log10) IU/mL at screening. Forty-eight study participants will be randomized 3:1 to receive SLGN (36 active and 12 placebo), and randomization will be stratified by HBeAg status. One-half of the study participants will be HBeAg positive (n=24) at screening, and the other half will be HBeAg negative (n=24). Enrollment of women (female sex at birth) is encouraged, with an enrollment goal of at least 14 women. The participants will be followed until Week 48.

The primary outcome of the study is achieving at least 1 log10 IU/mL decline in qHBsAg from baseline at the end of treatment (Week 24). The probability of achieving a decline ≥1 log10 IU/mL in the study population is deemed to be very low (<1%), and it is expected that none of the 12

placebo participants will achieve such decline. The primary analysis of qHBsAg decline will be conducted as a single-arm evaluation in the active SLGN arm and pooled across screening HBeAg statuses (N=36). The placebo arm will serve as a reference group for safety assessments and the analyses of exploratory markers.

The primary outcomes by Week 24 may be evaluated prior to the completion of the study. The primary analysis timeline will be driven by the last participant's completion of the primary outcome visit, rather than the study completion date. Results from the primary analysis on qHBsAg may be presented publicly, for example at a conference, when the data related to such analysis are complete, prior to study database finalization.

2.2 Hypotheses

- Administration of the oral TLR8 agonist SLGN will be safe and well-tolerated in participants with both CHB and HIV-1 on suppressive antiviral therapy for both viruses.
- TLR8 stimulation with SLGN will reduce hepatitis B surface antigen (HBsAg) titers in the blood of participants with both CHB and HIV-1 on suppressive antiviral therapy for both viruses.

2.3 Study Objectives

This Primary SAP addresses the following primary and secondary objectives in the study protocol. The secondary PK objectives will be analyzed outside of SDAC and their analysis will be defined in a separate SAP. Other study objectives in the protocol will be addressed in subsequent analysis plans.

Analyses for the primary objectives and the Secondary Objective 2 related to Week 24 will be finalized once the last participant has completed the Week 24 study visit and all related queries have been resolved. For the remaining objectives, the analyses will be finalized once the last participant has completed the Week 48 study visit, all queries have been resolved, and the study database closure/data lock has been completed.

2.3.1 Primary Objectives

1. To assess the safety and tolerability of treatment with SLGN administered once weekly by mouth for 24 weeks.
2. To determine the proportion of participants with ≥1 log10 IU/mL decline in quantitative HBsAg (qHBsAg) after SLGN treatment at Week 24.

2.3.2 Secondary Objectives

1. To determine the proportion of participants with ≥1 $\log_{10}$ IU/mL decline in qHBsAg at any time during the study after SLGN treatment initiation.
2. To determine the proportion of participants with ≥0.5 log10 IU/mL decline in qHBsAg after SLGN treatment at Week 24.
3. To determine the proportion of participants with ≥0.5 log10 IU/mL decline in qHBsAg at any time during the study after SLGN treatment initiation.

4. To evaluate the proportion of participants who achieve HBsAg loss after SLGN initiation and who sustain HBsAg loss during follow-up.
5. To evaluate changes in qHBsAg levels at Weeks 4, 12, 24, 36, and 48 after SLGN initiation and, separately, among the placebo recipients.
6. To determine the proportion of HBeAg positive participants at baseline who lose HBeAg at any time during the study, by study arm.
7. To determine the proportion of anti-HBe negative participants at baseline who develop anti-HBe at any time during the study, by study arm.
8. To determine the proportion of hepatitis B surface antibody (anti-HBs) negative participants at baseline who develop anti-HBs at any time during the study, by study arm.

2.4 Overview of Sample Size Considerations

The team anticipates 8% to achieve the primary outcome in the active arm and aims to rule out 0.5%. With 36 participants who initiate treatment in the active SLGN arm, there is 89% power to conclude that the proportion is greater than the null rate of 0.5% when the true proportion is 8% in a one-sided exact binomial test with a targeted significance level of 5%, using the normal approximation approach for power calculation (PASS 15 Version 15.0.4).

Up to six additional participants may be enrolled to ensure sufficient power for the primary analysis on qHBsAg, if there are unevaluable primary outcomes due to missing results. (See Section 5.1.3 table on handling of missing data.)

2.5 Overview of Formal Interim Monitoring

The study will undergo interim review at least annually by an ACTG-appointed Study Monitoring Committee (SMC), as described in the protocol. No formal interim reviews of efficacy data are planned for this study. The following is a guideline to be used to monitor safety data.

If any of the following safety criteria are not met at any time while the study treatment is ongoing for any of the study participants, then a review by the ACTG-appointed Study Monitoring Committee (SMC) will be triggered. The team and the site are blinded to treatment assignment, but the SMC can become unblinded to the treatment assignment. The worst AE outcome from each participant will be considered for the safety criteria below, and the participants will be monitored continually.

a) ≤2 participants experience Grade 3 AE that is deemed related to the study product as judged by the Core Team who will take into account the site's attribution.
b) ≤1 participant experiences a Grade 4 AE related to the study product as judged by the Core Team who will take into account the site's attribution.
c) None of the participants with death attributed to the study product as judged by the Core Team and/or the site.

3 Outcome Measures

3.1 Primary Outcome Measure(s)

1. [Primary Objective 1 on safety] Grade ≥2 AEs occurring out to scheduled Week 24 visit.

2. [Primary Objective 1 on tolerability] Premature discontinuation of treatment due to AEs.
3. [Primary Objective 2] Quantitative HBsAg (qHBsAg) decline ≥1 $\log_{10}$ from baseline at Week 24.

3.2 Secondary Outcome Measures

1. [Secondary Objective 1] Quantitative HBsAg (qHBsAg) decline ≥1 log10 from baseline at any time during the study.
2. [Secondary Objective 2] Quantitative HBsAg (qHBsAg) decline ≥0.5 log10 from baseline at Week 24.
3. [Secondary Objective 3] Quantitative HBsAg (qHBsAg) decline ≥0.5 log10 from baseline at any time during the study.
4. [Secondary Objective 4] HBsAg loss determined by the qualitative HBsAg assay at any time during the study not followed by any subsequent positive HBsAg result.
5. [Secondary Objective 5] qHBsAg change from baseline at Weeks 4, 12, 24, 36, and 48.
6. [Secondary Objective 6] HBeAg loss at any time during the study among the HBeAg positive participants at baseline.
7. [Secondary Objective 7] Anti-HBe gain at any time during the study among the anti-HBe negative participants at baseline.
8. [Secondary Objective 8] Anti-HBs gain at any time during the study among the anti-HBs negative participants at baseline.
9. [Safety] Detection of plasma HIV RNA > 50 copies/ml at weeks 2, 4, 24 and 48.
10. [Safety] Detection of plasma HBV DNA> 50 IU/ml at weeks 2, 4, 24 and 48.

For the visit weeks, protocol-defined visit windows will be used. There will be at least two submissions to ClinicalTrials.gov. The first submission will be timed with the analyses of the primary outcome measures. The second submission will cover the remaining secondary outcome measures.

4 General Considerations

- Baseline refers to study evaluation closest to Week 0 prior to initiation of study treatment.
- For summaries of outcomes at specified study visits, study visit windows as specified in Protocol Section 6.0 will be used, unless specified otherwise. In the event of multiple results within a study window, the result closest to the scheduled evaluation week will be used.
- Continuous variables will be summarized with min, Q1, median, Q3, and max, unless specified otherwise.
- Confidence intervals around proportions will be provided using the Clopper-Pearson method for binomial data.

5 Estimands and Estimation

The strategies for handling intercurrent events (e.g. treatment policy strategy, principal stratum strategy, composite variable strategy) are as described in ICH E9(R1) Addendum on Estimands and Sensitivity Analysis in Clinical Trials.

5.1 Primary Estimands

5.1.1 Estimand for Primary Objective 2.3.1.1

<table>
<tr><td colspan="2">Primary Objective 1 (safety): To assess the safety and tolerability of treatment with SLGN administered once weekly by mouth for 24 weeks.</td></tr>
<tr><td>Estimand description</td><td>Probability of experiencing at least one Grade ≥2 adverse event over 24 weeks after initiation of SLGN in adults with both chronic HBV and HIV-1.</td></tr>
<tr><td>Treatment</td><td>SLGN 3 mg once weekly for 24 weeks.</td></tr>
<tr><td>Target population</td><td>Analysis set</td></tr>
<tr><td>Adults with HIV-1 and chronic hepatitis B virus on suppressive effective antiviral therapy for HIV (ART) and HBV for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis, who initiate SLGN treatment.</td><td>All participants who meet trial eligibility criteria and initiate SLGN treatment following randomization.</td></tr>
<tr><td>Variable</td><td>Outcome measure</td></tr>
<tr><td>Occurrence of at least one Grade ≥2 adverse event over 24 weeks after treatment initiation.</td><td>Grade ≥2 adverse event (graded according to the NIAID DAIDS Table) out to study visit Week 24, per protocol-defined visit window.</td></tr>
<tr><td>Handling of intercurrent events</td><td>Handling of missing data</td></tr>
<tr><td>• Premature treatment discontinuation: All adverse events through 24 weeks are used to determine the variable (Treatment Policy Strategy).
• Pregnancy: Women who become pregnant are followed off treatment. Events through 24 weeks are used to determine the variable (Treatment Policy Strategy).
• Death: Death is defined as the worst adverse event, Grade 5 (Composite Variable Strategy).</td><td>For participants discontinuing study prior to Week 24, assume no additional adverse events occur after discontinuation.</td></tr>
<tr><td>Population-level summary measure</td><td>Analysis approach</td></tr>
<tr><td>Proportion.</td><td>Proportion calculated along with two-sided 95% confidence interval (CI) using Clopper-Pearson exact method for binomial data.</td></tr>
</table>

<u>Sensitivity Analysis</u>

- Handling of missing data: For participants discontinuing study prior to Week 24, censor follow-up at the last study visit.
- Analysis approach: Proportion estimated using the Kaplan-Meier method with Greenwood's formula for the variance to calculate 2-sided 95% CI.

5.1.2 Estimand for Primary Objective 2.3.1.1 on Tolerability

<table>
<tr><td colspan="2">Primary Objective 1 (tolerability): To assess the tolerability of 24 weeks of treatment with SLGN administered once weekly by mouth for 24 weeks.</td></tr>
<tr><td>Estimand description</td><td>Probability of premature discontinuation of SLGN due to adverse event(s) (intolerability of SLGN) in adults with HIV-1 and HBV.</td></tr>
</table>

Treatment	SLGN 3 mg once weekly for 24 weeks.
Target population	Analysis set
Adults with HIV-1 and chronic hepatitis B virus on suppressive effective antiviral therapy for HIV (ART) and HBV for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis, who initiate SLGN treatment.	All participants who meet trial eligibility criteria and initiate SLGN treatment following randomization.
Variable	Outcome measure
Premature discontinuation of SLGN due to adverse event(s).	Premature discontinuation of SLGN with reason reported as adverse event(s).
Handling of intercurrent events	Handling of missing data
• Premature treatment discontinuation: Incomplete treatments are included (Treatment Policy Strategy). • Death: If the cause of death is unrelated to SLGN, then treatment discontinuation due to death is not considered related to tolerability. Otherwise, death is deemed adverse event (Composite Variable Strategy).	For the participants who discontinue the study prior to Week 24 without meeting the outcome measure, assume that the SLGN was tolerable.
Population-level summary measure	Analysis approach
Proportion.	Proportion with a two-sided 95% confidence interval (CI) using Clopper-Pearson exact method for binomial data.

Sensitivity Analysis

- Handling of missing data: For participants discontinuing study prior to Week 24, censor follow-up at the last study visit.
- Analysis approach: Proportion estimated using the Kaplan-Meier method with Greenwood's formula for the variance to calculate 2-sided 95% CI.

5.1.3 Estimand for Primary Objective 2.3.1.2

Primary Objective 2: To determine the proportion of participants with ≥1 log10 IU/mL decline in quantitative HBsAg (qHBsAg) after SLGN treatment at Week 24.	
Estimand description	Probability of achieving qHBsAg decline ≥1 log10 IU/mL in qHBsAg from baseline to 24 weeks after initiation of SLGN in adults with HIV-1 and HBV.
Treatment	SLGN 3 mg once weekly for 24 weeks.
Target population	Analysis set
Adults with HIV-1 and chronic hepatitis B virus on suppressive effective antiviral therapy for HIV (ART) and HBV for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis, who initiate SLGN treatment.	All participants who meet trial eligibility criteria and initiate SLGN treatment following randomization.
Variable	Outcome measure

Quantitative HBsAg (qHBsAg) decline ≥1 log10 IU/mL measured 24 weeks after treatment initiation.	Binary outcome on quantitative HBsAg (qHBsAg) decline ≥1 log10 from baseline (Week 0) at visit Week 24, per protocol-defined visit window. If there is more than one result in this visit window, the one closest to the study visit Week 24 will be used.
Handling of intercurrent events	Handling of missing data
• Premature treatment discontinuation: All measurements through 24 weeks are used to determine the variable (Treatment Policy Strategy) • Pregnancy: Women who become pregnant are followed off treatment. Measurements through 24 weeks used to determine the variable (Treatment Policy Strategy). • Death: If the cause of death is deemed unrelated to SLGN, then all measurements through 24 weeks are used to determine the variable. If the cause of death is deemed related to SLGN, death is considered a failure to achieve decline. (Composite Variable Strategy).	• If a participant discontinues the study prior to Week 24 for reasons potentially related to study treatment: a. If no post-baseline result is available, then outcome is assigned as failure (<1 log10 decline). b. If any post-baseline result is available, the prior result closest to Week 24 will be carried forward as the outcome. • If a participant discontinues the study prior to Week 24 for reasons clearly unrelated to study treatment (e.g. participant moved away): a. If treated for at least 12 weeks and result(s) at or after Week 12 is (are) available, the prior result closest to Week 24 will be used as the outcome. b. Otherwise, missing completely at random is assumed. • If a participant's Week 24 result is missing while on study (e.g. missed visit), the prior result closest to Week 24 will be carried forward as the outcome • If the baseline result is missing, then missing completely at random is assumed.
Population-level summary measure	Analysis approach
Proportion.	Proportion with a two-sided **90**% confidence interval (CI) using Clopper-Pearson exact method for binomial data.

Supplementary Analysis

An additional analysis will be conducted, where the target population and the handling of intercurrent events are modified as follows.

Target Population	Adults with HIV-1 and chronic hepatitis B virus (HBV) on suppressive, dually-HBV-active antiretroviral therapy (ART) for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis, who complete 24 weeks of SLGN treatment.
Handling of Intercurrent Events	• Treatment discontinuation: Incomplete treatment is excluded (Principal Stratum Strategy). • Pregnancy: Follows the strategy for treatment discontinuation. • Death: Individual who is not alive through 24 weeks of SLGN treatment is not in the target population (Principal Stratum Strategy).

5.2 Key Secondary Estimands

5.2.1 Estimand for Secondary Objective 2.3.2.4

Secondary Objective 4: To evaluate the proportion of participants who achieve HBsAg loss after SLGN initiation and who sustain HBsAg during follow-up.	
Estimand description	Probability of achieving HBsAg loss after SLGN initiation.
Treatment	SLGN 3 mg once weekly for 24 weeks.
Target population	Analysis set
Adults with HIV-1 and chronic hepatitis B virus on suppressive effective antiviral therapy for HIV (ART) and HBV for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis, who initiate SLGN treatment.	All participants who meet trial eligibility criteria and initiate SLGN treatment following randomization.
Variable(s)	Outcome measure(s)
Conversion to negative HBsAg determined by the qualitative HBsAg assay at any time after initiation of SLGN, without any subsequent positive HBsAg result.	Binary outcome of conversion to negative HBsAg by the qualitative HBsAg assay at any time on study after initiation of treatment, without any subsequent positive HBsAg result.
Handling of intercurrent events	Handling of missing data
• Premature treatment discontinuation: All measurements are used to determine the variable (Treatment Policy Strategy) • Pregnancy: Women who become pregnant are followed off treatment. All measurements are used to determine the variable (Treatment Policy Strategy). • Death: All measurements up to death are used to determine the variable for the individual. Assume that the subsequent measurements do not change after death. (Composite Variable Strategy).	For participants discontinuing study prematurely without conversion to negative HBsAg, assume failure to convert after discontinuing the study.
Population-level summary measure	Analysis approach
Proportion.	Proportion with a two-sided **90**% confidence interval (CI) using Clopper-Pearson exact method for binomial data.

5.2.2 Estimand for Secondary Objective 2.3.2.5

Secondary Objective 5 for SLGN: To evaluate changes in qHBsAg levels at Weeks 4, 12, 24, 36, and 48 after SLGN initiation.	
Estimand description	Changes in qHBsAg from treatment initiation at 4, 12, 24, 36 and 48 weeks after treatment (5 separate estimands, one for each time).
Treatment	SLGN 3 mg once weekly for 24 weeks.
Target population	Analysis set

Adults with HIV-1 and chronic hepatitis B virus on suppressive effective antiviral therapy for HIV (ART) and HBV for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis, who initiate SLGN treatment.	All participants who meet trial eligibility criteria and initiate SLGN treatment following randomization.
Variables	Outcome measures
Changes in qHBsAg from initiation of SLGN at Weeks 4, 12, 24, 36 and 48 (5 separate variables).	Changes in qHBsAg from baseline (Week 0) at Weeks 4, 12, 24, 36 and 48 (5 separate outcome measures).
Handling of intercurrent events	Handling of missing data
• Premature treatment discontinuation: All measurements through 48 weeks are used to determine the variables (Treatment Policy Strategy) • Pregnancy: Women who become pregnant are followed off treatment. All measurements through 48 weeks are used to determine the variables (Treatment Policy Strategy). • Death: All available measurements up to death are used to determine the variables. For variables after death, the individual is deemed to be no longer in the target population. (Principal Stratum Strategy)	Assume missing completely at random for missing data at each week and only include available data.
Population-level summary measure	Analysis approach
Median change at each week.	At each week, median will be provided with lower and upper quartiles (Q1 and Q3).

Supplementary Analysis on Placebo

The same analysis will be conducted among placebo recipients. The target population and the analysis set are modified as follows.

Target Population	Adults with HIV-1 and chronic hepatitis B virus (HBV) on suppressive, dually-HBV-active antiretroviral therapy (ART) for ≥5 years, with quantitative hepatitis B surface antigen (qHBsAg) >1000 IU/mL, without evidence of advanced liver fibrosis or cirrhosis.
Analysis Set	All participants who meet trial eligibility criteria and initiate placebo following randomization.

6 Analysis of Other Objectives

Analyses of Secondary Outcome Measures 1, 3, 4, 6, 7 and 8 will take a similar analysis approach to what has been described above in Key Secondary Estimand Section 5.2.1.

- For Secondary Outcome Measure 6, the target population and the analysis set will be restricted to the participants who are HBeAg positive at baseline (Week 0). The analysis will be conducted by study arm.

- For Secondary Outcome Measure 7, the target population and the analysis set will be restricted to the participants who are anti-HBe negative at baseline (Week 0). The analysis will be conducted by study arm.
- For Secondary Outcome Measure 8, the target population and the analysis set will be restricted to the participants who are anti-HBs negative at baseline (Week 0). The analysis will be conducted by study arm. The analysis will be conducted by study arm.

Analysis of Secondary Outcome Measure 2 will take a similar analysis approach to what has been described above in Primary Estimand Section 5.1.3.

Analysis of Secondary Outcome Measure 5 will be analyzed as described above in Key Secondary Estimand Section 5.2.2. The analyses will be conducted by study arm.

7 Report Contents

1. CONSORT Diagram
2. Study history
    a. A summary of changes to and clarifications of the protocol.
    b. A brief summary of the SMC reviews.
3. Study entry
    a. Screening: Number of screenings for the study
    b. Accrual: Tables of accrual by month and by site
    c. Number of participants who did not start study treatment.
4. Baseline characteristics
    a. Demographics: age, sex at birth, gender identity, race, ethnicity, IV drug use, smoking status, country
    b. Weight and BMI
    c. HBV DNA viral load, qHBsAg, HBeAg status, HBV genotype and HBV diagnosis time (if available)
    d. HIV-1 RNA viral load, CD4+ and CD8+ T-cell count
    e. ARV regimen
    f. Liver function tests: total and direct bilirubin, ALT/SGPT, AST/SGOT, albumin
5. Study status
    a. Listing of premature study discontinuations with reasons. For premature discontinuations, the number of weeks on study will be provided.
6. Study treatment status
    a. Listing of premature study treatment discontinuations with reasons. For premature discontinuations, the number of weeks on study treatment will be provided.
7. Adverse events and deaths
    a. Summary of all adverse events defined in Section 7.2 of the protocol by MedDRA system organ class (SOC) and preferred term (PT) and by grade, by study arm.
    b. Summary of the participants who died, including primary cause of death with weeks from study entry, by study arm.
    c. Listing and narratives of deaths.
8. Pregnancies

   a. Listing and description of all available information related to pregnancy and outcome
9. Analysis of Primary Outcome Measure 1
   a. Primary analysis on safety as described in Section 5.1.1.
   b. Sensitivity analysis as described in the same section.
10. Analysis of Primary Outcome Measure 2
   a. Primary analysis on tolerability as described in Section 5.1.2.
   b. Sensitivity analysis as described in the same section.
11. Analysis of Primary Outcome Measure 3
   a. Primary analysis on Week 24 qHBsAg decline ≥1 log10 as described in Section 5.1.3.
   b. Supplementary analysis on the subset of the study population who complete 24 weeks of SLGN treatment, as described in the same section.
12. Analysis of secondary outcome measures
   a. Secondary Outcome Measure 1 on qHBsAg decline ≥1 log10 from baseline at any time during the study will be analyzed in a similar fashion to Secondary Outcome Measure 4 described in Section 5.2.1.
   b. Secondary Outcome Measure 2 on qHBsAg decline ≥0.5 log10 from baseline at Week 24 will be analyzed in a similar fashion to Primary Outcome Measure 3 described in Section 5.1.3
   c. Secondary Outcome Measure 3 on qHBsAg decline ≥0.5 log10 from baseline at any time during the study will be analyzed in a similar fashion to Secondary Outcome Measure 4 described in Section 5.2.1.
   d. Secondary Outcome Measure 4 will be analyzed as described in Section 5.2.1.
   e. Secondary Outcome Measure 5 will be analyzed as described in Section 5.2.2, by study arm.
   f. Secondary Outcome Measure 6 on HBeAg loss at any time on study will be analyzed in a similar fashion to Secondary Outcome Measure 4 described in Section 5.2.1, restricted to the participants who are HBeAg positive at Week 0, by study arm.
   g. Secondary Outcome Measure 7 on anti-HBe gain at any time on study will be analyzed in a similar fashion to Secondary Outcome Measure 4 described in Section 5.2.1, restricted to the participants who are anti-HBe negative at Week 0, by study arm.
   h. Secondary Outcome Measure 8 on anti-HBs gain at any time on study will be analyzed in a similar fashion to Secondary Outcome Measure 4 described in Section 5.2.1, restricted to the participants who are anti-HBs negative at Week 0, by study arm.
13. Other analyses
   a. For Primary Outcome 3 and Secondary Outcomes 1, 2, 3 and 4, any occurrences in the placebo arm will be reported.
   b. Number of participants with detection of plasma HIV RNA > 50 copies/ml at weeks 2, 4, 24 and 48 will be provided by study arm.
   c. Number of participants with detection of plasma HBV DNA> 50 IU/ml at weeks 2, 4, 24 and 48 will be provided by study arm.