Peking University Clinical Research Institute

Statistical Analysis Plan

Customer Name:	**Ascletis Pharmaceuticals Co., Ltd.**
Project title:	**Evaluate ritonavir-intensified ASC08 tablets in combinatior pegylated interferon and Ribavirin in treatment-naive patients with chronic hepat virus genotype 1 infection Multicenter, open-label phase III clinical study of the efficac safety in non-cirrhotic patients**
Main content:	**Protocol design, statistical analysis**
Contact person:	**Yan Xiaoyan 010-82805838-1022**
Responsible Person:	**Prof. Yao Chen**

Date: March 21, 2017

1.1 Protocol design

1.1.1 Test design

Participate in the design of the protocol and design the trial protocol jointly with the leading site, including whether the control, blind method, hypothesis test method, setting of main efficacy indicators and other links are used.

1.1.2 Sample Size Calculation

The required sample size was calculated from the primary efficacy measures and trial design using PASS11 software.

1.2 Statistical Analysis

1.2.1 Biostatistics and Analysis Report

The statistician designates a biostatistician to complete the corresponding statistical analysis and prepare the corresponding analysis table and list. The biostatistician completes the statistical analysis report.

1.2.2 Statistical Analysis Plan and Tables

The statistician expands and designs a statistical analysis plan (SAP) based on the statistical methods provided in the protocol. The SAP will provide a reasonable description of the analysis population, an objective analysis of the study's efficacy and safety, and a presentation of statements and summaries to make the abstract of the data contained in the final study report understandable and allow for appropriate statistical testing.

The SAP will be drafted by the Biostatistician, reviewed and revised by the Sponsor's representative and the Principal Investigator, and finalized. The SAP served as a guideline for programming, analysis, and report writing. The SAP is subject to 2 rounds of sponsor review prior to finalization.

The biostatistician prepares the sample of statistical tables, which will describe the format of the upcoming tables and can truly describe the information reflected in the analysis results. These tables have a certain format on the basis of SAP. The form will also be sent to the investigator and sponsor for further review and discussion.

1.2.3 Statistical procedures

The statistician's biostatistician and programmer will prepare the corresponding programming plan, analyze the program, simulate the run and produce

the statistical analysis and summary table according to the above SAP.

1.2.4 Statistical Analysis of Data

Generates the draft analysis report based on SAP and program run results.

1.2.5 Procedure and report review

Check possible logic errors in the program, browse the draft analysis report, perform the analysis twice, and write the quality control report.

1.2.6 Statistical Report

The Biostatistician will submit the draft analytical report with the complete analytical results to the Sponsor, solicit comments from the Sponsor and the Investigator, make corresponding revisions, and finalize it.

1.3 Project Management

1.3.1 Sponsor Meetings

The sponsor and the statistician discuss some main points, reiterate some necessary reports, review the schedule, and clarify other issues of common concern.

1.3.2 Project Schedule Management

The statistician will designate a project manager within the company to contact the sponsor. His responsibility is to carry out daily communication between the sponsor and the statistician's project team, and to convey the progress of the project, problems arising, suggestions and decisions to solve the problems to the sponsor. The statistician shall discuss the project schedule and relevant issues with the Data Management Project Team on a regular basis to make scientific preparations for the project.

1.3.3 **Periodic Reports**

The PM shall prepare the monthly report and send it to the Sponsor on a regular basis, in the format fixed by the statistician or provided by the Sponsor itself, and report at an interval of 4 weeks.

1.3.4 Consumables

Perform and archive essential office consumables for the project.

2 Project Overview

Project Overview: A Multi-centered, Open Label, Phase III Study on Efficacy, Safety of Ritonavir-boosted ASC08 (Danoprevir) in Combination With Peg-IFN and RBV in Treatment-Naive Non-Cirrhotic Patients Who Have Chronic Hepatitis Genotype 1

Design: Single arm open

Data collection: Tigermed EDC

Random system: None

This offer is a supplemental interim analysis offer.

3 Project Team Composition

Project Team Composition	Number of people
Senior Statistician (SBS)	1
Statistician (BS)	1
Programmer (PR)	1

4 Service Content

Service Content	SBS	BS	PR
	Man-hour	Man-hour	Man-hour
Write statistical analysis plan	**0**	**0**	**0**
Data arrangement and docking	**0**	16	24
Review Statistical Analysis Plan	**0**	**0**	**0**
Writing Statistical Analysis Procedures	**0**	**0**	**0**
Writing Statistical Analysis Report (Chinese)	**12**	48	0
Statistical report review	**16**	0	0
Total	28	64	24