Statistical Analysis Plan: Mock-up Subject Data Listings

Version 3.0, 14DEC2018

Protocol Number: SCB01A-22

An Open-Label, Phase II Study to Evaluate the Efficacy and Safety of SCB01A in Subjects with Recurrent or Metastatic Squamous Cell Head and Neck Cancer Who Have Failed Platinum-Based Treatment

Protocol version: 1.0 /19-Dec-2016
Sponsor: SynCore Biotechnology Co., Ltd.

The Mock-up "PATIENT DATA LISTINGS" is planned according to ICH E3, in which relevant CSR section is 16.2. The words shadowed below are for notifications, or to be revised, or variables/format/footnotes to be included.

All listing will be sorted by (1) Eligibility {Eligible subjects, Screen failures} (2) Subject ID (3) Visit No. (4) Item No.

Note:

(1) The subject ID is auto generate as Site ID - Screening Number - Stage code and Subject Number (□-S□□-□□□) for eligible subject or as Site ID - Screening Number (□-S□□) for screening failure

Site ID.: one-digit number □

Site ID	Site Name
1	Taipei Medical University Hospital (TMUH)
2	National Cheng Kung University Hospital (NCKUH)
3	Taipei Veterans General Hospital (TVGH)
4	Taipei Medical University Shuang Ho Hospital (TMUSHH)

Screening number: two-digit number □□ assigned sequentially from 01 for each site
Stage code: one-digit number □ {1 - Stage I, 2 - Stage II}
Subject number: two-digit number □□ assigned sequentially from 01 for each site

(2) DP/AG:

D denotes maximum treatment dose level

12: Level 1 (12 mg/m^2) 9: Level 1a (9 mg/m^2) 7: Level 1b (7 mg/m^2)
18: Level 2 (18 mg/m^2) 15: Level 2a (15 mg/m^2) 12: Level 2b (12 mg/m^2)
24: Level 3 (24 mg/m^2) 20: Level 3a (20 mg/m^2) 16: Level 3b (16 mg/m^2)

P denotes population with value of either one below
I: Intent-to-treat (ITT) population
P: Per-protocol (PP) population, ITT included

A denotes age in Y/O
Age [Y/O] = year of informed consent – year of birth

G denotes gender,
M: male,
F: female

(3) Date format: YYYY-MM-DD

(4) For Visit Name, C(c) denotes cycle (c), D(d) denotes day (d)

Visit No.	Visit Name	Visit Code	Planned Visit Day
0	Screening Visit	SV	-28 ~ -1
1.01	Cycle 1 Day 1	C1D1	1
1.08	Cycle 1 Day 8	C1D8	7±1 days after C1D1
1.15	Cycle 1 Day 15	C1D15	14±2 days after C1D1
□.01	Cycle □ Day 1	C□D1	21±1 days after C□1D1 □=□-1
□.08	Cycle □ Day 8	C□D8	7±1 days after C□D1
□.15	Cycle □ Day 15, □**=1, 2, 3 only**	C□D15	14±2 days after C□D1

Visit No.	Visit Name	Visit Code	Planned Visit Day
	End of Treatment (EOT) / Early Withdrawal (EW)	EOT / EW	EOT: 21±2 days after C[k]1D1 or 14±2 days after C[k]1D8, [k]=[c]-1 EW: after the last treatment dose
	Toxicity Follow-Up Visit (TFU)	TFU	28±3 days after the last treatment dose
99.1	Follow-Up Visit 1 (FU1)	FU1	21±3 after EOT/EW
99.2	Follow-Up Visit 2 (FU2)	FU2	21±3 after FU1-W3
99.3	Follow-Up Visit 3 (FU3)	FU3	21±3 after FU2-W6
99. [F]	Follow-Up Visit [F] (FU[F])	FU[F]	Every 9 weeks ±7 days
66.[x][x]	Unscheduled Visit (UV)	UV	

[c]: cycle number where [c]≥2, [F]: assigned sequentially from 4, [x][x]: assigned sequentially from 01

(5) For the visit/assessment days and hour (like AE Onset Day), they were derived by formula below

Day (D) = date–first dosing date + 1 if date ≧ 1st dosing date, or = date–first dosing date if date < 1st dosing date

Day/Hour = [visit/assessment date/time – 1st dosing date/time + 1] , if date ≧ 1st dosing date/time,

Day/Hour = [visit/assessment date/time – 1st dosing date/time] , if date < 1st dosing date/time,

Duration in days/hours = [end date/time – onset date/time + 1] if end date/time is active

Duration in days/hours = [end date/time – onset date/time] if end date/time is inactive

(6) Full term for 'Primary System Organ Class' in AE:

Code	Full Term
Blood	Blood and lymphatic system disorders
Cardi	Cardiac disorders
Conge	Congenital, familial and genetic disorders
Ear a	Ear and labyrinth disorders
Endoc	Endocrine disorders
Eye d	Eye disorders
Gastr	Gastrointestinal disorders
Gener	General disorders and administration site conditions
Hepat	Hepatobiliary disorders
Immun	Immune system disorders
Infec	Infections and infestations
Injur	Injury, poisoning and procedural complications
Inves	Investigations
Metab	Metabolism and nutrition disorders
Muscu	Musculoskeletal and connective tissue disorders
Neopl	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Nervo	Nervous system disorders
Pregn	Pregnancy, puerperium and perinatal conditions
Psych	Psychiatric disorders
Renal	Renal and urinary disorders
Repro	Reproductive system and breast disorders
Respi	Respiratory, thoracic and mediastinal disorders
Skin	Skin and subcutaneous tissue disorders
Socia	Social circumstances
Surgi	Surgical and medical procedures
Vascu	Vascular disorders

(7) Full term for Laboratory Measurements:

- Hematology

LBSPID	Code	Full Term
LB01	RBC	RBC

LBSPID	Code	Full Term
LB02	HGB	Hemoglobin
LB03	HCT	Hematocrit
LB04	PLAT	Platelet
LB05	NEUT	Absolute neutrophil count (ANC)
LB06	MCV	Mean Corpuscular Volume (MCV)
LB07	MCH	Mean Corpuscular Hemoglobin (MCH)
LB08	MCHC	Mean Corpuscular Hemoglobin Concentration (MCHC)
LB09	WBC	WBC
LB10	NEUTLE	Neutrophils
LB11	LYMLE	Lymphocytes
LB12	MONOLE	Monocytes
LB13	EOSLE	Eosinophils
LB14	BASOLE	Basophils

- Biochemistry

LBSPID	Code	Full Term
LB15	BILI	Bilirubin (total)
LB16	ALP	Alkaline Phosphatase
LB17	ALT	Alanine aminotransferase
LB18	AST	Aspartate aminotransferase
LB19	GGT	Gamma-glutamyl transferase (GGT)
LB20	ALB	Albumin
LB21	PROT	Total protein
LB22	CREAT	Creatinine
LB23	BUN	Blood urea nitrogen (BUN)
LB24	URIAC	Uric Acid
LB25	CK	Creatinine Kinase (Ck)
LB26	TROPONT	Troponin-T
LB27	TROPONI	Troponin-I
LB28	SODIUM	Sodium (Na+)
LB29	K	Potassium (K+)
LB30	CA	Calcium (Ca++)
LB31	CL	Chloride (Cl)
LB32	GLUC	Glucose
LB33	TRIG	Triglycerides (TG)
LB34	AMYLASE	Amylase
LB35	CREATCLR	Creatinine Clearance
LB36	CHOL	Total Cholesterol
LB37	HDL	High-Density Lipoprotein (HDL)
LB38	LDL	Low-Density Lipoprotein (LDL)
LB39	LIPASE	Lipase

- Coagulation

LBSPID	Code	Full Term
LB40	PT	Prothrombin Time
LB41	INR	Prothrombin Intl. Normalized Ratio

- Urinalysis

LBSPID	Code	Full Term
LB42	UPH	pH
LB43	APPEAR	Appearance
LB44	COLOR	Color
LB45	SPGRAV	Specific gravity
LB46	VISC	Viscosity
LB47	TURB	Turbidity
LB48	KETONES	Ketones
LB49	UBILI	Bilirubin
LB50	OCCBLD	Blood

LBSPID	Code	Full Term
LB51	UGLUC	Glucose
LB52	UPROT	Protein
LB53	NITRITE	Nitrite
LB54	UROBIL	Urobilinogen
LB55	LEUKASE	Leukocyte esterases
LB56	BACT	Bacteria
LB57	CASTS	Casts
LB58	CRYSTALS	Crystals
LB59	EPIC	Epithelial Cells
LB60	URBC	RBC
LB61	UWBC	WBC

(8) For clinical relevant,

- CS denotes 'abnormal and clinically significant',
- NCS denotes 'abnormal but not clinically significant'

(9) General Abbreviations

Code	Full Term
A, NA, N/A	Not Applicable
U, UK, U/K	Unknown
O, OG, O/G	Ongoing
D, ND, N/D	Not Done
M, MS, M/S	Missing
MH	Medical History
AE	Adverse Event
CM	Concomitant Medication
INC[X][X]	Inclusion Criterion [X][X]
EXC[X][X]	Exclusion Criterion [X][X]

16.2 Patient Data Listings

16.2.1 Discontinued Subjects

16.2.1.1 Screen Failures
Criteria not met (IE)

16.2.1.2 Study Termination of Eligible Subjects
Domain [DS], including
First Treatment Date/Time,
Last Treatment Date/Time,
End date of treatment phase,
Study Duration (see 14.1.2),
Status (Study Completed or Early Termination),
Reason

16.2.1.3 Inform Consent Date, Visit Dates

16.2.2 Protocol Deviations

16.2.2.1 Protocol Deviations – Inclusion/Exclusion Subjects

16.2.2.2 Protocol Deviations

16.2.3 Eligible Patients Excluded from the Safety/Efficacy Analysis

16.2.3.1 Eligible Patients Excluded from Intent-To-Teat (ITT) Population

16.2.3.2 Eligible Patients Excluded from Per-protocol (PP) Population

16.2.3.3 Eligible Patients Excluded from Pharmacokinetics (PK) Population

16.2.4 Demographic Data and Baseline Characteristics

16.2.4.1 Demographic Data

16.2.4.2 Smoking Status and Betelnut Consumption

16.2.4.3 Head and Neck Squamous Cell Carcinoma (HNSCC) History & Tumor Staging
including Disease Duration (see 14.1.4)

16.2.4.4 Virology Test and Pregnancy Test

16.2.4.5 General Medical History

16.2.5 Medication History and Concomitant Medications

16.2.5.1 Cancer Therapy – Surgery

16.2.5.2 Cancer Therapy –Anti-Cancer Medication

16.2.5.3 Cancer Therapy – Radiotherapy

16.2.5.4 Medication History & Concomitant Medications

16.2.6 Study Drug Administration

16.2.6.1 BSA Calculation, SCB01A IV Infusion and Dose Modification

Cycle, Day, Dose Level, BSA (m^2) = [Height (cm) x Body Weight (kg)/3600]½

16.2.6.2 BSA Calculation, SCB01A IV Infusion and Dose Modification - Comment / Not Done Reason

16.2.6.3 Study Drug Exposure
(See 14.1.6)

16.2.7 Efficacy Data

16.2.7.1 Radiological Image Assessment - Target Lesions

16.2.7.2 Radiological Image Assessment - Non-Target Lesions

16.2.7.3 Radiological Image Assessment - Not Done Reason

16.2.7.4 Radiological Image Assessment - Best Tumor Size Change in Target Lesions

16.2.7.5 Tumor Response Assessment
Including Target Lesions, Non-Target Lesions, Overall Response

16.2.7.6 Survival Follow-up

16.2.7.7 Cancer Therapy Follow-up

16.2.7.8 Overall Efficacy Endpoints
Including Objective Response (Rate of CR+PR),
Date of Death (+ denotes the last survival observation date when death is not observed),
Overall Survival (+ denotes censored at the last survival observation date),
Date of Progression (+ denotes the last tumor assessment date when progression is not observed),
Progression-Free Survival (+ denotes censored at the last tumor assessment date),
Best Overall Tumor Response

16.2.8 Adverse Event (AE) and Serious Adverse Event (SAE)

16.2.8.1 Treatment Emergent AEs

Variables: In addition to event description and general AE profiles (onset date, resolution date, severity, relationship to study treatment, action taken to study treatment, seriousness, outcome), the patient data listing will also present the MedDRA(version 19.1) body system and preferred term, onset day, and AE duration [days]

Footnote:

- ***Onset Day = onset date – the first treatment dosing date + 1***
- ***AE duration [days]***
  = resolution date - onset date (while resolved)
  =study exit date – onset date (while not resolved, noted with '+')

16.2.8.2 Treatment Emergent AEs – DLT

16.2.8.3 Treatment Emergent AEs – Grade ≥3 AEs

16.2.8.4 Treatment Emergent AEs – Treatment Related AE
Treatment Related is defined as Definitely Related, Probable Related, or Possibly Related

16.2.8.5 Treatment Emergent AEs – Treatment Modified AE
Treatment Modified is defined as Treatment Infusion Interrupted, Treatment Omitted, Dose Reduced, Treatment Discontinued

16.2.8.6 Serious Adverse Event

16.2.8.7 General Medical History of Subjects with SAE

16.2.8.8 Medication History & Concomitant Medications of Subjects with SAE

16.2.9 Laboratory Measurements

16.2.9.1 Laboratory Measurements – Summary in Standard Unit

16.2.9.2 Laboratory Measurements – Hematology

16.2.9.3 Laboratory Measurements – Biochemistry

16.2.9.4 Laboratory Measurements – Coagulation

16.2.9.5 Laboratory Measurements – Urinalysis

16.2.9.6 Laboratory Measurements – Comment and Not Done Reason

16.2.10 Other Safety Measurements

16.2.10.1 Vital Signs, Body Weight and ECOG Performance Status

16.2.10.2 Nerve Conduction Velocity (NCV)

16.2.10.3 12-Lead Electrocardiogram (ECG, EKG)

16.2.10.4 Physical Examination

16.2.10.5 Physical Abnormalities

16.2.11 Pharmacokinetic Analysis

16.2.11.1 Pharmacokinetic Blood Sampling Date/Time

16.2.12 Comments

16.2.12.1 Comments