Statistical Analysis Plan

Compound Name:	**TEW-7197**
Protocol no:	**MP-VAC-105(version 1.2)**
IRB No:	**18-0122**
NCT Number	**NCT03704675**
Study Title:	**A randomized, open, cross-over design clinical trial to investigate the safety, tolerability, and pharmacokinetics of TEW-7197 after a single oral administration of TEW-7197 200 mg under fed or fasting conditions in healthy male subjects**

Statistical analysis	• Demographic and baseline characteristics By TEW-7197 sequence, descriptive statistics (number of subjects, mean, standard deviation, range, minimum, median, maximum) were tabulated for demographic information such as age and sex and physical measurement/baseline characteristics such as height, weight, body mass index, drinking level and blood donation, and frequency and percentage were tabulated for categorical data. In order to confirm validity of randomization and subsequent analysis, statistical significance was assessed using an independent sample T test or Mann-Whitney test for continuous variables by sequence. • Pharmacokinetic analysis After calculating pharmacokinetic parameters by patient, descriptive statistics such as mean, standard deviation and CV% were presented by dose group. Descriptive statistics were presented for mean, standard deviation and CV% by treatment (fed/fasting), and the point estimate and 90% confidence interval of the mean difference between treatments were estimated by using log-transformed C_{max} and AUC_t. • Safety evaluation For adverse events and adverse drug reactions that occurred in this study, frequency (number of subjects), percentage and number of events were presented according to SOC and PT by dose group and treatment. Frequency (number of subjects), percentage and number of events were also presented for adverse events and adverse drug reactions according to SOC and PT by severity. Chi-square test or McNemar's test was used to evaluate a statistical significance between treatments. For vital signs, physical examination, 12-lead ECG, echocardiography and each item of clinical laboratory evaluations, descriptive statistics (number of subjects, mean

	standard deviation, minimum, median, maximum and change from baseline (difference, change rate)) were tabulated by each measurement time, and for categorical data, frequency and percentage were tabulated. Concomitant medication was presented with lists.

I hereby certify that the translated summary of the SAP to be substantially true and accurate to the original Korean version of the SAP in regards to the contents.

Kyounghee Kim : _____ 10 / FEB / 2020

Clinical Project Manager. Name / Signature — Date (DD/MMM/YYYY)

Sungjin Hwang : _____ 10/FEB/2020

Chief Medical Officer. Name / Signature — Date (DD/MMM/YYYY)