Title: The Real World Analysis of Drug-Drug Interaction of Grazoprevir/Elbasvir in

Treatment of Chronic Hepatitis C patients in Taiwan

Protocol No: MISP#57751

Date: 28 July 2018

This is a multi-center, retrospective study.
Numbers of site & Subjects: 5 hospitals in Taiwan and 400 patients

Patient enrolled criteria: Patients treated with grazoprevir/elbasvir during August 2017 to July 2018 are candidates of study subjects.
All the required study information will be recorded with detailed chart review.

Items of record: Patient's Demographics, HCV viral load, HCV Genotype, Fibrosis status, HCC status, Child-Pugh score for cirrhosis, CHC treatment History, HBV co-infection, HIV co-infection, solid organ transplantation status, co-morbid diseases, medication used before and through the 12 weeks or 16 weeks of grazoprevir/elbasvir including class and number.

Evaluation tool: HEP Drug Interactions (www.hep-druginteractions.org)

Assessment of co-medications:
Category 0: Classification not possible due to lack of information
Category 1: No clinical interaction possible
Category 2: May require dose adjustment/closer monitoring
Category 3: Co-administration not recommended or contraindicated

Detailed co-medications before and through 12 weeks or 16 weeks of grazoprevir/elbasvir treatment will be reviewed and recorded. The assessment of DDIs will be evaluated by HEP Drug Interactions *(www.hep-druginteractions.org)* and recorded according to the suggested categories. Co-morbid diseases will be recorded before grazoprevir/elbasvir treatment according organ systems.

To assess the number of patients at risk for a clinically relevant DDI, the ratio of patients with at least one predicted DDI between co-medication and grazoprevir/elbasvir will be calculated.

Statistical Analysis
Data will be expressed as percentages. To assess the number of patients at risk for a clinically relevant DDI, the ratio of patients with at least one predicted DDI between co-medication and grazoprevir/elbasvir will be calculated. The difference will be compared by Chi-square or Fisher exact test. Two-tailed P values less than 0.05 is

considered to be significant. SPSS version 17 will be used for statistical analysis.