Cover Page

Study Title: Phase IV Comparison of Combigan BID vs Simbrinza TID in Subjects Currently Treated with Latanoprost for Open-Angle Glaucoma or Ocular Hypertension

NCT # 02167035

10MAY2018

Statistical Analysis Plan

Analysis Populations

There are four populations included in this analysis: (1) Safety Population, (2) Intent-to-treat Population (ITT), (3) Modified Intent-to-treat Population (mITT) and (4) Per-protocol Population (PP).

The 'Safety Population' included all enrolled subjects.

The 'Intent-to-treat Population' included all enrolled subjects randomized to masked study medication.

The 'Modified Intent-to-treat Population' included all ITT subjects who attended Visits 1, 2 and 3 (minimally).

The 'Per-protocol Population' included all randomized subjects that completed all scheduled study visits without a major protocol violation/deviation.

Analysis Assumptions and Conditions

Summary tables (descriptive statistics and/or frequency distributions) were provided for all baseline variables and efficacy variables. Continuous variables were described by descriptive statistics (n, mean, standard deviation, range and median). Frequency distributions (counts and percentages) of subjects within each category were provided for categorical variables.

No replacement of missing values was performed for this study.

Select Specific Variables Discussion

Intraocular Pressure (IOP)

Study Eye Definition: Study eye was determined to be the eye which qualified for study inclusion according to the inclusion and exclusion criteria; if both eyes qualified then the eye with the worse IOP at baseline (10:00 AM time point) was denoted as the study eye. If both eyes had the same IOP at baseline, then the right eye was denoted as the study eye.

Diurnal Calculation: A diurnal value was determined only when all three (3) time point's worth of IOP study eye data were present (8:00 AM, 10:00 AM and 4:00 PM) for any given subject at any given visit.

Ocular Symptoms/Tolerability Questionnaire

Scoring: Individual categorical responses for symptom severity were converted to numeric responses using the following conversion parameters. All "N/A" and blank responses were not used when calculating the Ocular Symptoms/Tolerability Questionnaire mean scores, etc.

Questions 1-10 Response	Converted Numeric Response
None	0
Mild	1
Moderate	2
Severe	3