A prospective, multi-center, open-label study to evaluate the safety, tolerability and efficacy of OTX-TIC (travoprost) intracameral implant in subjects with primary open-angle glaucoma (OAG) or ocular hypertension (OHT)

NCT04360174

July 28, 2020

11. STATISTICAL ANALYSIS

11.1. Statistical and Analytical Plans

This study is not designed to show statistical significance, therefore, there will be no statistical analyses completed. There will be a general Statistical Plan that will briefly summarize how the data will be presented, i.e., descriptive statistics, etc.

11.2. Determination of Sample Size

For this Phase 1 study, no formal sample size calculations have been performed. A sample size of 5 subjects is considered sufficient to inform on safety of the product.

11.3. Analysis Datasets

The safety population will consist of all subjects receiving the OTX-TIC implant. All safety and efficacy analyses will be performed on the safety population.

11.4. Demographics and Baseline Data

Subject disposition will be presented, including the number of subjects screened, enrolled and treated. The number of subjects who completed the study and reasons for discontinuation will be summarized.

Demographic and baseline characteristics (including disease and medical history) will be summarized.

11.5. Safety Analyses

Safety will be assessed by adverse events, subject ocular comfort assessment, Investigator global tolerance score and other ocular-related outcomes.

Adverse events will be coded using Medical Dictionary for Regulatory Activities (MedDRA) by system organ class and preferred term. Separate summaries will be made for adverse events that are related to the injection procedure and the intracameral implant. In addition, serious adverse events will be summarized.

Summaries of other safety related outcomes will be provided.

11.6. Efficacy Analyses

[redacted]

11.7. Exploratory Analyses

[redacted]