

**ALLEGRO OPHTHALMICS, LLC
PROTOCOL DME 202B
Statistical Analysis Plan Summary**

**A PHASE 2 MULTICENTER, RANDOMIZED, CONTROLLED,
DOUBLE-MASKED CLINICAL TRIAL DESIGNED TO
EVALUATE THE SAFETY AND EXPLORATORY EFFICACY
OF LUMINATE® (ALG-1001) AS COMPARED TO AVASTIN®
IN THE TREATMENT OF DIABETIC MACULAR EDEMA**

**March 17, 2017
SPONSOR:**

**IND : 119548
Allegro Ophthalmics, LLC
31473 Rancho Viejo Rd, Suite 204
San Juan Capistrano, CA 92675
Phone: (949) 940 - 8130
Fax: (949) 940 - 8121**

Allegro Chief Medical Officer:

**Vicken Karageozian, MD
Office Telephone: (949) 940-8130
Cell Phone: (949) 295-2135**

Allegro Medical Safety Physician:

**Barbara Wirostko, MD
Cell Phone: (347) 453-1521
Email: barbarawirostko@trialrunners.com**

Allegro Executive Clinical Director:

**Melvin Sarayba, MD
Office Telephone: (949) 444-5727
Office Fax: (949) 940-8121
Cell Phone: (312) 415-0201**

1.1 Statistical Methods Planned in the Protocol and Determination of Sample Size

1.1.1 Statistical and Analytical Plans

Descriptive statistics were used to tabulate and summarize study outcomes. Background and demographic characteristics were presented. Continuous variables were summarized by descriptive statistics (sample size, mean, standard deviation [SD], median, minimum, and maximum). Discrete variables were summarized by frequencies and percentages. AEs were summarized by presenting the number and percentage of subjects having at least 1 such AE. Any other information collected (such as severity or relationship to study drug) was listed as appropriate.

Any statistical tests performed were used to explore treatment differences or associations between variables of interest. Such analyses were exploratory. Exploratory logistic models were performed on binary endpoints, such as the gain of ≥ 15 letters or resolution of macular edema.

All statistical analyses were programmed using SAS[®] software version 9.4 (SAS Institute, Cary, NC, USA). The SAP is provided in [Appendix 16.1.9](#).

1.1.2 Determination of Sample Size

Since this was a phase 2 exploratory clinical study, no formal hypothesis testing was performed. The sample size was determined based on establishing a reasonable number of subjects to provide adequate safety and efficacy information to proceed to the next phase of clinical development.