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Control/Tracking Number: 07-A-6382-ARVO

Activity: Abstract

Current Date/Time: 12/1/2006 4:52:13 PM

A Phase 2, Randomized, Controlled Study of Squalamine Lactate in Combination with Visudyne® in Patients with Subfoveal Choroidal Neovascularization Associated with Age-Related Macular Degeneration

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Abstract:

Purpose: To evaluate the safety profile and efficacy of squalamine lactate (SQ) at three different doses in combination with photodynamic therapy with verteporfin (PDT) compared with controls over 29 weeks.

Methods: 46 Subjects over 50 years of age with a diagnosis of subfoveal choroidal neovascularization (CNV) associated with AMD (all subtypes) that were deemed suitable for PDT were treated with intravenous SQ or vehicle weekly for 4 infusions, followed by 5 monthly infusions. A baseline visual acuity (VA) of 34 to 78 ETDRS letters was required for study participation. Subjects were randomly assigned to treatment with either 10, 20, or 40 mg of SQ plus PDT or vehicle control plus PDT. PDT was administered to all subjects at week 3. If deemed necessary by the investigator, subjects could be re-treated with PDT at weeks 15 and 27. Subjects were withdrawn from the trial if their VA deteriorated by 15 ETDRS letters at 2 consecutive study visits.

Results: Mean age was 77 years, and over 60% of the subjects were women. Thirty-five percent of the subjects had predominantly classic disease, 17% had minimally classic disease and 48% had active occult CNV. Eighty percent of the study subjects were classified as having bilateral disease. There were no drug-related serious adverse events. Most adverse events (AEs) involved reactions at the infusion sites, and were judged to be mild in severity. Ten of the 46 subjects had AEs deemed "probably related" to study drug by the investigators, including one retinal detachment. There was no difference in the percentages of related AEs between the study groups receiving different squalamine doses, suggesting that, at these levels,

there was no dose-related effect on safety parameters. SQ + PDT treatment in PDT eligible subjects resulted in a higher level of stable VA than PDT treatment alone, although the difference did not achieve statistical significance.

Conclusions: These findings suggest that SQ in combination with PDT therapy is safe and well tolerated.

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Author Disclosure Block: A. DelConte, Genaera Corporation, E; M.J. Gast, Genaera Corporation, E; A. Eaton, Honoraria, R; D. Rosberger, None; W. Yarnall, Genaera Corporation, E; R. Katz, Honoraria, R.

Reviewing Codes (Complete): 104age-relatedmaculardegeneration:clinicalresearch-RE

Presentation Preference (Complete): Paper #1, Poster #2

Keyword (Complete): 411 age-related macular degeneration ; 450 choroid: neovascularization ; 678 retina

Clinical Trial and Newsworthy (Complete):

***Clinical Trial :** Yes

: www.clinicaltrials.gov

***Newsworthy :** No

Support (Complete):

***Support :** Genaera Corp

Status: Complete

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