

ARCHWAY STUDY

...for wet AMD



Wet Macular Degeneration

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Phase III, multi-center, randomized, visual assessor-masked active-comparator study of the efficacy, safety, and pharmacokinetics of the port delivery system with ranibizumab in patients with neovascular age-related macular degeneration

INCLUSION CRITERIA:

- At least 50 years of age with initial diagnosis of exudative nAMD within 9 months prior to the screening visit
- Previous treatment with at least three anti-VEGF intravitreal injections for nAMD per standard of care within 6 months prior to the screening visit
- Demonstrated response to prior anti-VEGF intravitreal treatment since diagnosis, as evidenced at screening by overall decrease in nAMD disease activity detected on SD-OCT, and stable or improved BCVA
- BCVA of 34 letters or better (20/200 or better approximate Snellen equivalent)

EXCLUSION CRITERIA:

- **Study Eye:**
 - History of any intervention treatment for AMD
 - Prior treatment with Visudyne®, radiation therapy, or transpupillary thermotherapy
 - Previous treatment with corticosteroid intravitreal injection
 - Aphakia or absence of the posterior capsule
 - Previous laser used for AMD treatment
 - Intraocular surgery (including cataract surgery) within 3 months preceding the randomization visit
- **Either Eye:**
 - Treatment with anti-VEGF agents other than ranibizumab within 1 month prior to the randomization visit
 - Prior participation in a clinical trial involving anti-VEGF drugs within 6 months prior to the randomization visit, other than ranibizumab

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This research is not being conducted by the Columbus Chalmers P. Wiley Ambulatory Care Center. The research has not been reviewed by the Institutional Review Board of the Chalmers P. Wiley VA. The VA is not responsible for any costs incurred by participating in the research study.