

Oral treatment for wet AMD enters phase 2 study

X-82, an orally administered, dual inhibitor of vascular endothelial growth factor (VEGF) and platelet-derived growth factor (PDGF) in development for treatment of wet age-related macular degeneration (AMD) and solid tumors, has entered phase 2 studies, developer Tyrogenex (Palm Beach Gardens, Fla.) said in a press release. Patients enrolled in the study had previously been treated with Eylea (aflibercept, Regeneron, Tarrytown, N.Y.).

Preliminary data show that X-82 does not exhibit dose-limiting toxicity. This phase 2 study, dubbed APEX, is a randomized, double-masked, placebo-controlled, dose-finding phase 2 study being conducted throughout the U.S. at 20 sites and 5 sites in the U.K. The study is designed to evaluate the safety and efficacy of X-82 in the prevention of vision loss due to wet AMD. APEX is expected to enroll 132 subjects. The primary endpoint of the APEX study is the mean change in visual acuity score from day 1 to 52 weeks after randomization. Another key endpoint is the reduction of the number of injections needed for the duration of the study.