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Dedicated to Eye Disease Cure and Education

Valacyclovir Therapy Study in Patients with Herpes Simplex Virus Uveitis

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We previously showed that long-term oral acyclovir therapy could reduce the prevalence of recurrent uveitis in patients who are having their recurrent uveitis on the basis of herpes simplex virus. (*Reference*: Rodriguez A, Power WJ, Neves RA, Foster CS: 1994. Long-Term Systemic Acyclovir in the Management of Recurrent Herpes Simplex Keratouveitis. In:*Advances in Ocular Immunology* (R.B. Nussenblatt, S.M. Whitcup, R.R. Caspi and I. Gery, eds., pp 465-468, Elsevier Science B.V.) This study, however, was not randomized, placebo-controlled, double masked. And while we are convinced, on the basis of this experience that, just as in the case of recurrent herpes simplex keratitis, so too in recurrent herpes simplex uveitis long-term chronic oral prophylactic maintenance anti-viral therapy is safe and effective in reducing recurrences of inflammation, we feel obligated now to subject this belief to rigorous scientific testing through a randomized, double masked, placebo-controlled clinical trial.

We have chosen to use the active metabolite of acyclovir, valacyclovir, for purposes of this study. GlaxoWellcome Company is sponsoring the study in that they are providing drug and masked placebo for the purposes of this study. The dosing will be with one gram of Valtrex each day for a minimum of two years. Patients who have recurrent herpes simplex uveitis (diagnosed on the basis of classic clinical characteristics or positive polymerase chain reaction analysis) will be randomized to receive either active drug (ValtrexÎ) or placebo. The patients will be monitored regularly, as are all of our uveitis patients, and will also additionally be seen in the event of increasing signs or symptoms suggesting uveitis. The follow-up period is two years, and the primary endpoint is the number of recurrences of intraocular inflammation. A secondary endpoint is visual acuity. Obviously, safety of long-term use of ValtrexÎ will also be of interest, but concerns about