



FLORIDA EYE
Microsurgical Institute, Inc.

FOR IMMEDIATE RELEASE

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**FLORIDA EYE MICROSURGICAL INSTITUTE ANNOUNCES POSITIVE TRIAL RESULTS OF
NEW TREATMENTS FOR SERIOUS EYE CONDITIONS SUFFERED BY MILLIONS**

SEEKS PARTICIPANTS FOR PHASE III OF CLINICAL TRIAL

Boynton Beach, FL, May 19th, 2009.... The Florida Eye Microsurgical Institute is pleased to announce that its patients involved in a clinical trial of a new medication developed to treat geographic atrophy (GA) are showing very promising results.

“What’s so exciting about the findings of this trial,” explains Dr. Randy Katz, Florida Eye Microsurgical Institute’s retinal and macular degeneration specialist, “is that there are currently no FDA-approved treatments for GA. Over time macular degeneration robs its victims of their sight and can render them legally blind. OT-551, is the first eye drop to ever be tested in a clinical trial as a treatment for dry AMD, and its results thus far are extremely encouraging.”

OT-551 is a topically-dosed, patented small molecule that acts on oxidative stress and disease-induced inflammation,” says Dr. Katz, “and when administered to patients, it has shown to be successful for reducing moderate vision loss (i.e., 15 letters or more on the ETDRS chart) in patients with GA who were treated with OT-551 compared with a placebo.”

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The twelve month findings from the two-year trial give great hope to millions of Americans who suffer with GA. “Patients with this condition lose their ability to read, drive and see the faces of their friends and families,” says Dr. Katz. “The real possibility that OT-551 will help treat GA is tremendous.”

An independent Data and Safety Monitoring Committee is scheduled to review the interim results of the Phase II study later this month, and once the final results are reported, Phase III of the trial will begin.

Also very promising – another clinical drug trial for GA involving Florida Eye patients. Produced by Sirion Therapeutics, Inc., the drug, fenretinide, reported positive results from its Phase II trial. The analysis of the orally administered drug for the treatment of GA associated with age-related macular degeneration compared the growth rate of GA lesions, as measured by retinal photography, in patients treated with daily doses of placebo of 100 mg or 300mg of fenretinide.

The results? “Amazing,” says Dr. Katz. The drug, an oral vitamin A binding protein antagonist, is believed to halt the accumulation of retinol (vitamin A) toxins through affinity for retinal-binding protein. It is also believed to slow the formation and accumulation of toxic byproducts thought to be responsible for vision loss in conditions like GA. According to Dr. Katz and the study findings, the data showed slower growth of the GA lesions for the 300mg dose for all lesions of size at entry. This trend was evidenced as early as six months into the trial and increased over time. Among the

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subpopulation of 78 patients who reached the 18 month study visit, the median growth rate of the lesions in the 300mg group was 22.7% versus 41.6% in the placebo group, representing a 45% reduction in median lesion growth rate at month 18 of the trial. The current study is powered to detect a 50% reduction in lesion growth rate at 24 months.

Also encouraging, slower lesion growth was observed in the 100mg group among test subjects who had lesions smaller than the median baseline at entry. According to Dr. Katz, “these findings suggest that early intervention may improve outcomes in halting the progression of the disease.”

Because of the promising results of the Phase II study, Sirion is continuing the current study to its conclusion, and plans are already underway for Sirion to meet with its scientific advisors and the FDA to design an appropriate Phase III program for the new drug.

More positive news from Sirion – the FDA has granted Fast Track designation for fenretinide for the treatment of GA associated with AMD. What does this mean for those involved in the trials?

According to Dr, Katz, Sirion’s ability to use Fast Track designation in its work has “the potential to accelerate the development of fenretinide for the treatment of geographic atrophy, which, as we know, is a condition with no currently approved treatment. Now that Sirion has received the green light to incorporate Fast Track into their treatment studies, we are extremely optimistic that Sirion will bring a much

needed treatment option to patients living with GA.”

In May, Dr. Katz will present a poster at the May 6th, 2009 annual meeting of the Association for Research in Vision and Ophthalmology in Ft. Lauderdale, where he will present a summary of the fenretinide trial’s top-line results.

The Phase III trial is slated to begin in 2010, and Dr. Katz is currently seeking patients who may qualify to be a part of the trial. “There is no other treatment at this time for the condition,” says Dr. Katz, “so with the initial promising results patients have nothing to lose and plenty to gain. The drug company covers all of the associated costs of the trial, including medication and sometimes even transportation costs.” Anyone interested in becoming a trial participant is urged to contact Dr. Katz at Florida Eye at (561) 737-5500.

Aside from his work with these groundbreaking clinical trials, Dr. Katz treats a variety of other eye conditions, such as diabetic retinopathy, and he is the *only* specialist in the area to treat premature babies for retinopathy of prematurity (ROP), a disorder of the blood vessels of the retina, when, if left untreated will result in irreversible blindness. He is involved in numerous national clinical treatment trials and he currently serves on the Diabetes Advisory Council for the state of Florida (appointed by Florida Governor Charlie Christ) as its ophthalmologic specialist. Dr. Katz also serves as the Medical Director for the Florida Eye Microsurgical Institute.

The Florida Eye Microsurgical Institute offers a full range of comprehensive ophthalmologic care, including routine eye care and examinations, pediatric eye care, dry eyes, advanced corneal, retinal and cataract procedures, laser treatments, glaucoma and diabetic procedures, and various other sophisticated treatments. With its own pediatric wing and fully accredited outpatient surgical center in Boynton Beach, the Institute has additional offices in Boca Raton, Wellington and Juno Beach. For more information on the Institute, its physicians and current clinical trials, please contact Gwen Cohan at (561) 736-5050 and visit www.fleyedocs.com.

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