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For Immediate Release

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***Comparative-Effectiveness Study Confirms New Treatment for Diabetic Macular Edema
Ranibizumab Injections Plus Laser Therapy Results in Dramatic Visual Improvement***

Researchers have shown that ranibizumab (Lucentis) eye injections, often in combination with laser treatment, result in better vision than laser treatment alone for diabetes-associated swelling of the retina.

Laser treatment alone has been the standard care for the past 25 years. But nearly 50 percent of patients who received this new treatment experienced substantial visual improvement after one year, compared with 28 percent who received the standard laser treatment. The study involved 52 clinical sites within the Diabetic Retinopathy Clinical Research Network (DRCR.net), supported by the National Eye Institute (NEI) and the National Institute of Diabetes and Digestive and Kidney Diseases, part of the National Institutes of Health.

Retina Associates of Kentucky has been working with the National Institutes of Health for more than five years participating in this important study. We are currently involved in several other significant studies related to retina and eye health. “We are elated with the results which demonstrate the reversal of vision loss and even blindness in some patients. This is indeed encouraging for those who suffer from various degrees of vision loss as a result of diabetes,” said Thomas Stone, MD, Principal Investigator and Partner of Retina Associates of Kentucky.

“These results indicate a treatment breakthrough for saving the vision of people with diabetic macular edema,” said Neil M. Bressler, M.D., chair of the DRCR.net and chief of the Retina Division at the Wilmer Eye Institute, Johns Hopkins University, Md. “Eye injections of ranibizumab with prompt or deferred laser treatment should now be considered for patients with characteristics similar to those in this clinical trial.”

Diabetic retinopathy is the most common cause of vision loss in working-age Americans. This condition damages the small blood vessels in the eye's light-sensitive retinal tissue. When these damaged blood vessels begin to leak fluid near the center of the retina, known as the macula, macular edema occurs. The macula provides detailed central vision used for activities such as reading, driving, and distinguishing faces. In macular edema the retinal tissue swells, which can lead to vision loss if left untreated.

Laser treatment of the retina has been the standard care for diabetic macular edema since an NEI-supported study in 1985 showed it to be beneficial. However, recent small short-term studies have revealed the visual benefits of eye injections of medications that block a chemical signal that stimulates blood vessel growth, known as vascular endothelial growth factor (VEGF). These studies have indicated that repeated doses of anti-VEGF medications, such as ranibizumab, may prevent blood vessels from leaking fluid and causing macular edema. The DRCR.net study, published online April 27 in *Ophthalmology*, confirms preliminary results and provides evidence of the treatment's effectiveness in combination with laser therapy through at least one year of follow up.

“This comparative-effectiveness study demonstrated that a new treatment can protect and, in many cases, improve the vision of people with diabetic macular edema,” said NEI Director Paul A. Sieving, M.D., Ph.D.

The current study included a total of 854 eyes of 691 people, who had one or both eyes treated. Participants, who were on average in their early 60s, were diagnosed with type 1 or 2 diabetes and macular edema. They were randomly assigned to one of four study groups: sham injections plus prompt laser treatment within one week; ranibizumab injections plus prompt laser treatment; ranibizumab plus deferred laser treatment after six months or more; or injections of corticosteroid medication known as triamcinolone (Trivaris) plus prompt laser treatment.

Ranibizumab injections could be given as often as every four weeks, and triamcinolone injections or laser treatments could be given as often as every 16 weeks. In general, treatment was continued until a participant's vision or retinal thickness returned to normal, or additional treatment did not improve vision or retinal swelling.

After one year, nearly 50 percent of eyes treated with ranibizumab and prompt or deferred laser treatment showed a substantial visual improvement. People could read at least two additional lines on an eye chart with the treated eye, or letters that were at least one-third smaller than they could read before the study treatment. Fewer than 5 percent of eyes in these groups experienced a visual loss of two or more lines. The results were similar whether patients received prompt or deferred laser treatment with the ranibizumab injections.

In contrast, about 30 percent of eyes that received laser treatment alone or triamcinolone plus laser showed a visual improvement of two or more lines on an eye chart, while 13 to 14 percent of eyes in these groups had a visual loss of two or more lines.

Although participants in all three injection groups had a greater decrease in retinal thickness after

one year than with laser treatment alone, patients who received triamcinolone injections had greater complication rates. About 30 percent of people in the triamcinolone group developed high eye pressure that required medications, and about 60 percent developed cataracts that required surgery.

Few participants who received eye injections of ranibizumab had eye-related complications, such as an infection inside the eye likely caused by the injections, or worsening of a retinal detachment that existed prior to beginning treatment. The study found that eye injections of ranibizumab were not associated with any serious risks such as heart attack or stroke. DRCR.net researchers will continue to monitor the study participants for at least three years to obtain additional information about the safety and effectiveness of these macular edema treatments.

Find more information about this clinical trial (NCT00444600) at www.clinicaltrials.gov.

Soundbites and b-roll, including interview with and footage of study participant, are available for media by calling the NEI Office of Communication at (301) 496-5248 or by satellite on Tuesday, April 27, 2010 at 1:00-1:15 pm EDT and 4:00-4:15 pm EDT on coordinates Galaxy 16 Transponder: 14 D/L 3980 Vertical C-Band Analog Audio 6.2/6.8.

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The National Eye Institute, part of the National Institutes of Health, leads the federal government's research on the visual system and eye diseases. NEI supports basic and clinical science programs that result in the development of sight-saving treatments. For more information, visit www.nei.nih.gov.

The National Institute of Diabetes and Digestive and Kidney Diseases, part of NIH, conducts and supports basic and clinical research and research training on some of the most common, severe and disabling conditions affecting Americans. The Institute's research interests include diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition, and obesity; and kidney, urologic and hematologic diseases. For more information, visit www.niddk.nih.gov.

The National Institutes of Health (NIH) — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical, and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

About Retina Associates of Kentucky

Retina Associates of Kentucky's physicians and staff diagnose and treat many retina disorders, with specialization in retina detachments, macular degeneration, diabetes-related conditions and ocular histoplasmosis. Retina Associates of Kentucky Research Division engages in research studies on national and international levels, working in collaboration with other research centers such as the National Eye Institute, National Institute of Health, and the Diabetic Retinopathy Clinical Research Network. Although our home office is in Lexington, we have satellite offices located in Ashland, Prestonsburg, Somerset, Richmond, Harlan, Corbin, Campbellsville, and Danville.