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Research at The Methodist Hospital contributes to FDA-approval of Lucentis™ for wet age-related macular degeneration

HOUSTON—(June 30, 2006)—Research conducted by retina surgeons at The Methodist Hospital has contributed to FDA approval of a new wonder drug for patients affected by one of the leading causes of blindness in people over 60.

Dr. David M. Brown and his team at Vitreoretinal Consultants at The Methodist Hospital was the top enrolling site worldwide for the clinical studies that helped lead to today's U.S. Food and Drug Administration (FDA) approval of Lucentis™ (ranibizumab), an injectable treatment for neovascular wet age-related macular degeneration (AMD). AMD is one of the leading causes of blindness in people over 60 in the United States.

“With Lucentis, we now have a treatment option that has the potential to significantly improve vision for patients with wet AMD,” said Brown. “We are very pleased to have contributed to the development of this important new treatment option for wet AMD, and grateful to the patients in Houston and the surrounding areas who participated in the Lucentis clinical trials.”

Lucentis is designed to block new blood vessel growth and leakiness, which lead to wet AMD, by binding to and inhibiting VEGF-A, a protein that is believed to play a critical role in the formation of new blood vessels. Wet AMD affects the macula, the portion of the eye responsible for the central vision required for everyday activities such as reading, driving and recognizing faces. Symptoms include blurred, gray or blank

spots in the center of the visual field and distortion that makes edges or lines appear wavy. The FDA approval of Lucentis is based on data from two large Phase III clinical trials, in which Dr. Brown and his colleagues enrolled the most patients. In these studies:

- Approximately 95 percent of patients treated with Lucentis improved vision (defined as the gain of 15 letters or more in visual acuity) or maintained (defined as the loss of less than 15 letters in visual acuity) at one year, as measured on the Early Treatment of Diabetic Retinopathy (ETDRS) eye chart, the standard method of quantifying visual acuity.
- Up to 40 percent of patients treated with Lucentis achieved vision of 20/40 or better, the standard requirement for a driver's license in most states.
- The majority of patients treated with Lucentis found it easier to do more near and far vision-related activities, and some patients reported improvement in vision seven days after the first treatment with Lucentis.

In addition to data from the two pivotal studies, data from several other studies were included in the FDA submission. AMD is a major cause of central visual loss and is one of the leading causes of blindness in people over 60. The National Eye Institute estimates that there are 1.7 million people with the advanced form of AMD in the United States and that this prevalence will grow to 2.95 million by 2020.

AMD occurs in two forms: dry and wet. While all cases begin as the dry form, wet AMD accounts for about 85 percent of all AMD-related blindness and can result in sudden and severe vision loss. The dry form is associated with atrophic cell death of the central retina or macula. The wet form is caused by growth of abnormal blood vessels that leak fluid and blood under the macula causing scar tissue that destroys the central retina.

About The Methodist Hospital

The Methodist Hospital in Houston is one of the nation's largest private, non-profit general hospitals. Dedicated to providing the highest level of patient care, Methodist has a 90 year legacy of medical breakthroughs, such as the world's first multiple-organ transplant in the 1960s, gene therapy for prostate cancer, and the first islet cell transplants in Texas.

Methodist is ranked among the country's top centers in seven specialties in *U.S News & World Report's 2005 America's Best Hospitals* issue. The hospital ranked in more specialties than any other hospital in Texas, and is 14th on the list for ophthalmology.

Methodist is primarily affiliated with Weill Medical College of Cornell University and New York Presbyterian Hospital, two of the nation's leading centers for patient care, medical education and research. Methodist also is affiliated with the University of Houston. For more information, call (713) 790-3333 or visit www.methodisthealth.com.