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Newsletter from the Macular Degeneration Foundation, Inc.  
P.O. Box 531313 Henderson, NV 89053  
<http://www.eyesight.org>

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## GENENTECH, INC ANNOUNCES LUCENTIS EFFICACY

On May 16, 2006 Dawn Kalmar and Devra Nanes from Genentech's corporate relations hosted representatives from the MD Foundation. Optimism regarding the FDA approval of Lucentis, a new drug for the wet form of MD, was the topic of conversation. A tour of part of the Genentech campus provided a "close-up" look at this pharmaceutical facility. Although with 33 buildings and 10,000 employees, we just had a glimpse of what actually takes place in such an industry. The recent news release from Genentech makes up the content of this issue's newsletter:

South San Francisco, California (June 2, 2006) Genentech, Inc. (NYSE: DNA) announced today that a Phase IIIb clinical study of a quarterly dosing regimen of the investigational drug Lucentis<sup>®</sup> (ranibizumab) for the treatment of wet age-related macular degeneration (AMD) met its primary efficacy endpoint by preventing vision loss as measured by mean change in visual acuity from baseline to month 12. In this study, called PIER, patients receive Lucentis (0.3 mg or 0.5 mg respectively) or sham injections once per month for the first three months followed thereafter by doses once every three months for a total of 24 months. One-year data from this study were presented today at the Retinal Physician Symposium in the Bahamas. The pivotal Phase III studies of Lucentis (MARINA and ANCHOR) evaluate a monthly treatment schedule.

"The results of the Lucentis pivotal studies have changed the expectations for the treatment of wet AMD," said Hal Barron, M.D., Genentech senior vice president, Development and chief medical

officer. "While the PIER regimen provided a 16-letter benefit compared to sham, the data suggest that treating patients on a quarterly basis may be less effective than monthly or individualized dosing. Data from ongoing Phase IIIb studies and emerging results from our Investigator Sponsored Trials should help us learn more about the optimal dosing regimen for patients."

The wet form of macular degeneration is caused by growth of abnormal blood vessels, also known as choroidal neovascularization (CNV) or ocular angiogenesis, under the macula. These vessels leak fluid and blood and cause scar tissue that destroys the central retina. This results in a deterioration of sight over a period of months to years.

Lucentis<sup>®</sup> (ranibizumab) is a humanized therapeutic antibody fragment developed at Genentech and designed to bind and inhibit VEGF-A, a protein that is believed to play a critical role in angiogenesis (the formation of new blood vessels). Lucentis is designed to block new blood vessel growth and leakiness, which lead to wet AMD disease progression and vision loss. Lucentis is being developed by Genentech and the Novartis Ophthalmics Business Unit for diseases or disorders of the eye.

#### About Lucentis Pivotal Phase III Studies:

Lucentis has been studied in two randomized, controlled, double-masked Phase III clinical trials. Together, these trials evaluate Lucentis for the treatment of all types of wet AMD. At one year in both studies:

- \* Lucentis demonstrated an improvement of at least 15 letters in vision compared to the control groups.
- \* Approximately 95 percent of patients treated with Lucentis maintained or improved vision at one year.
- \* The majority of patients treated with Lucentis experienced a letter improvement of zero or more compared to the control groups.
- \* Up to 40 percent of those treated with Lucentis achieved a visual acuity of 20/40 or better.

At two years, the improvement in vision (as measured by visual acuity endpoints) among patients treated with Lucentis in the MARINA study was maintained while there was further deterioration of vision among patients in the control group. At least 90 percent of those treated with Lucentis at year two maintained or improved vision compared to approximately 53 percent in the control arm.

As discussed, the Phase IIIb SAILOR study of Lucentis is currently enrolling at approximately 110 sites in the United States. In this study, all eligible and enrolled patients will receive Lucentis (there is no non-Lucentis control arm). This study will enroll up to 5,000 patients with new or recurrent active subfoveal wet AMD until they receive the FDA's response to our application. Once they receive the FDA's response, and provided it is an approval, there will be a 30 day grace period during which patients will be transitioned from Lucentis study drug provided by Genentech to commercially available drug. Patients who participate in the SAILOR study will be monitored with a minimum of two follow-up visits at six months and 12 months. Safety events will be collected at each of these visits. A list of sites participating in SAILOR is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (identifier #: NCT00251459) or by calling toll-free 1-888-662-6728.

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#### OPTOTABS THE SUPPLEMENT OF CHOICE

We appreciate the support many of our subscribers have provided to the Macular Degeneration Foundation by the purchase of the OPTOTABS formula. This supplement provides the formula identified by the National Institute of Health as high-level antioxidant and also includes lutein and zeaxanthin which have been found beneficial in later studies. To order this product on line go to [www.optogon.com](http://www.optogon.com) or call 1-800-924-4393.

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#### CONTACTING MDF

To speak to a support representative directly, you may call 1-888-633-3937. If you reach our voice mail, please speak slowly and distinctly.

#### ORDERING BOOKS & TAPES

When purchasing items from Amazon.com, please remember to use the MDF search box located at <http://www.eyesight.org/Books/books.html> . By simply originating your search from our website, Amazon rewards the Foundation with a small commission from each product you order. Thank you.

#### MAKING CONTRIBUTIONS:

Please make checks payable to Macular Degeneration Foundation, Inc., P.O. Box 531313, Henderson, Nevada 89053, or you may use your credit card on our web site <http://www.eyesight.org/Donations/donations.html> . Your contributions make our services available as a support system for macular degeneration patients in the following ways:

1. We provide toll-free lines for personal contact assistance.
2. We mail brochures and other printed materials upon request.
3. We support an award-winning web site that provides the latest up-to-date information.
4. We fund research proposal grants to provide therapies for both the wet and dry form of AMD. Contributions marked "research" are used 100% for research.

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MDF was founded in 1992 by Edmund J. Aleksandrovich Ph.D (a victim of macular degeneration). It provides MD patients and their families with the information necessary to understand the disease, the latest news concerning ways to cope with the disease, and supports the efforts of researchers to find a cure.

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