



## **FOR IMMEDIATE RELEASE**

### **Alcon to Initiate New Anecortave Acetate Clinical Trials for Age-Related Macular Degeneration**

*Studies Will Assess Effectiveness of Investigational Therapy  
in Slowing Progression from Dry to Wet Form*

**Fort Worth, Texas – November 13, 2003** – Alcon, Inc. (NYSE:ACL) will initiate two new phase III studies of **Retaane™** (anecortave acetate for depot suspension) for treatment of age-related macular degeneration (AMD) – the most common cause of blindness in people over the age of 60. The new trials will evaluate the safety and efficacy of treatment every six months with the investigational drug **Retaane™** Depot versus placebo in a group of patients with advanced dry (or non-exudative) AMD who are at risk of progressing to wet (or exudative) AMD. After completion of enrollment, the studies will occur over a period of four years and will include approximately 2,500 patients who will be enrolled at 100 sites worldwide. Enrollment is scheduled to begin in January 2004. Alcon stated that the U.S. Food and Drug Administration (FDA) has given "Fast Track" designation to the development of Anecortave Acetate for this indication, because it represents a significant unmet medical need for a serious condition.

"These new trials represent uncharted territory for AMD therapy," said Jason S. Slakter, MD, of the Manhattan Eye, Ear and Throat Hospital and Chairman of the Anecortave Acetate Clinical Study Group. "Though not as severe a disease as the wet form of AMD, dry AMD may progress into wet AMD and therefore lead to extensive vision loss. Development of a treatment for people with dry AMD who have been identified as having high risk of progressing to wet AMD could be a breakthrough for the disease."

### **What is AMD?**

"Macular degeneration" describes several eye disorders characterized by damage to the macula – the light-sensitive cells near the center of the retina at the back of the eye. The macula is responsible for our ability to see with enough detail to read, drive, watch television and perform other activities that require focused, straight-ahead vision. When the cells of the macula degenerate and malfunction, the result is an increasing loss of central vision. Today, AMD is the leading cause of blindness in industrialized nations, primarily because there is a lack of effective treatments for the disease.

Dry AMD accounts for up to 90 percent of all cases of AMD. It occurs when the light-sensitive cells in the macula slowly die, gradually blurring central vision in the affected eye. Dry AMD typically develops slowly. Vision loss may be mild at first, becoming more noticeable over time. There is no approved medical treatment for dry AMD, and though it usually does not result in severe loss of vision or blindness, people with the disease may have difficulty recognizing faces and need additional light for "close-up" tasks like reading. Over time, dry AMD can progress to the wet form of the disease.

Wet AMD results from the rapid growth of abnormal blood vessels – called choroidal neovascular (CNV) lesions – under and towards the center, or macula, of the retina, the light-sensitive tissue in the back of the eye. As the fragile new vessels grow and proliferate, they

frequently leak blood and fluid that accumulates under and lifts the macula. The resulting vessel growth and fluid accumulation separates the retina from its anchoring tissue and causes rapid damage. Consequently, vision is distorted or destroyed. About 200,000 new cases of wet AMD are reported each year in the United States.

### **Method of Action**

Anecortave Acetate belongs to a class of compounds known as angiostatic cortisenes. Anecortave Acetate works by slowing or stopping the growth of new blood vessels, which leads to less leakage and less retinal damage. **Retaane™** 15 mg Depot is currently in clinical trials to evaluate its safety and efficacy in the treatment of the wet form of AMD. A recently completed two-year study in patients with wet AMD who received treatment with **Retaane™** 15 mg Depot every six months showed inhibition of all aspects of CNV lesion growth.

**Retaane™** 15 mg Depot is the only potential treatment for wet AMD that is administered onto the outer surface of the back of the eye using a specially designed curved, blunt-tipped cannula that does not pierce the eyeball. Unlike other investigational approaches to the treatment of AMD, the method of delivery for **Retaane™** Depot – called posterior juxtascleral depot or PJD – avoids the risk of intraocular infection and retinal detachment, the most common side effects associated with injecting therapeutic agents directly into the eye. To date, over 700 patients have been treated with anecortave acetate using PJD with no serious treatment-related side effects.

“The safety of the drug combined with the safety of posterior juxtascleral depot administration and a dosing frequency of every six months make **Retaane™** Depot very appropriate for chronic use,” said Donald J. D’Amico, MD, a Retina Specialist at the Massachusetts Eye and Ear Infirmary and Chairman of the Independent Safety Committee for Anecortave Acetate. “Taken together, these are extremely important factors in the selection of a therapy for long-term studies such as these.”

The FDA’s fast track designation is intended to address reviewing an investigational therapy that could treat an unmet medical need for a serious or life-threatening condition. The benefits of fast track status include: the opportunity to schedule more frequent meetings with the FDA to receive feedback on development plans; the option to submit a New Drug Application (NDA) piece-by-piece instead of all at once; and the option of submitting substitute endpoints for the study evaluation purposes.

### **About Alcon**

Alcon, Inc. is the world's leading eye care company. Alcon, which has been dedicated to the ophthalmic industry for over 50 years, develops, manufactures and markets pharmaceuticals, surgical equipment and devices, contact lens solutions and other vision care products that treat diseases, disorders and other conditions of the eye.

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### **Caution Concerning Forward-Looking Statements**

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, relating principally to our ability to complete clinical trials for Anecortave Acetate and file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and the expected benefits of Anecortave Acetate in treating exudative age-related macular degeneration (AMD). These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by our forward-looking statements. These statements reflect the views of our management as of the date of this press release with respect to*

*future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that might cause future results to differ include, but are not limited to, the following: we may never submit an NDA for Anecortave Acetate to the FDA, or submission and/or approval of the NDA may take longer than we expect; treatments developed by other companies may reach the market sooner or prove to be more effective than Anecortave Acetate; challenges inherent in new product marketing; and government regulation and legislation. You should read this press release with the understanding that our actual future results may be materially different from what we expect. Except to the extent required under the federal securities laws and the rules and regulations promulgated by the Securities and Exchange Commission, we undertake no obligation to publicly update or revise any of these forward-looking statements, whether to reflect new information or future events or circumstances or otherwise.*

**For information, please contact:**

Doug MacHatton – Alcon Investor Relations  
(800) 400-8599

Mary Dulle – Alcon Public Relations  
(817) 551-8058