



**For Immediate Release**

**Anecortave Acetate Demonstrates Significant Long-Term Efficacy in Wet Age-Related Macular Degeneration Patients**

- ***New two-year data reveal prevention of vision loss and inhibition of lesion growth***

**Fort Worth, Texas – August 18, 2003** – Alcon, Inc. (NYSE: ACL) reported today that long-term use of its investigational new drug, **RETAANE™** 15 mg (anecortave acetate for depot suspension), preserves vision, prevents severe vision loss and inhibits lesion growth in patients with wet age-related macular degeneration (AMD).

Henry L. Hudson, M.D., F.A.C.S., an ophthalmologist at the Retina Centers, P.C. in Tucson, Arizona, and an investigator in the study, presented 24-month, phase II/III study data today at the American Society of Retina Specialists (ASRS) annual meeting. "This new data adds to and confirms the previously reported 12 month findings which showed that a 15mg treatment of **RETAANE™** has the potential to safely and effectively preserve sight in and deliver tangible benefits to wet AMD patients. This is a significant milestone toward an improved standard of care for these patients," said Dr. Hudson.

AMD is one of the leading causes of blindness in the world. AMD destroys central vision, which is used to read, drive and perform other activities that require fine, sharp vision. Approximately 250,000 new U.S. cases of the "wet" or exudative form of AMD occur annually. Wet AMD occurs when new, leaky blood vessels grow towards the center, or macula, of the eye's light-sensitive inner layer, the retina. The resulting fluid accumulation separates the retina from its anchoring tissue, resulting in damage that can quickly lead to the loss of central vision.

"The 24-month data reaffirm the potential value of **RETAANE™** 15 mg for treating this devastating, difficult to control disease," said Stella Robertson, Ph.D., Alcon's Vice President of Pharmaceutical Products Research and Development. "Because the treatment options for patients with wet AMD are so limited, the potential **RETAANE™** 15 mg brings could prove to be a major advance in fighting wet AMD."

**RETAANE™** works by slowing or stopping the growth of new blood vessels, which leads to less leakage and less retinal damage. In the study, 73 percent of patients treated with **RETAANE™** 15 mg (anecortave acetate for depot suspension) had stable or improved vision based on measures from the logarithm of the minimum angle of resolution (logMAR) test, a standard AMD

vision test, from baseline to 24 months after treatment, significantly more than the 47 percent of patients in the placebo group ( $p=0.035$ ).

Patients treated with **RETAANE™** 15 mg (anecortave acetate for depot suspension) had no increase in growth of the classic component of the subfoveal choroidal neovascular membrane (CNV) between months 12 and 24, and the total lesion size remained stable over this period. Additionally, at 24 months, in the sub-group of patients with the more aggressive, predominantly classic CNV lesions, no patients treated with **RETAANE™** 15 mg had severe vision loss ( $\geq 6$  lines loss) compared to a 23 percent rate in the placebo group, ( $p=0.023$ ).

Patients received **RETAANE™** 15 mg (anecortave acetate for depot suspension) or placebo every six months, during an in-office procedure known as a posterior juxtascleral depot (PJD). During PJD, the investigator uses a specially designed cannula to place the suspension onto the outer surface of the back of the eye directly behind the macula. This method of delivery allows the drug to diffuse across the sclera and choroid into the macular portion of the retina over a period of six months. In contrast, other investigational therapies require direct injection into the eye as frequently as nine to 12 times annually.

According to a study of PJD presented at ASRS by investigator Peter K. Kaiser, M.D., an ophthalmologist at the Cole Eye Institute at the Cleveland Clinic in Ohio, this delivery method was found to be an effective way to administer **RETAANE™** 15 mg (anecortave acetate for depot suspension). In more than 500 procedures performed in five clinical trials to date, investigators found that PJD safely administered the drug over the macula, delivered adequate drug levels for up to six months and did not cause any identified clinically relevant safety issues. An independent safety committee that provides ongoing review for these studies determined that no clinically relevant adverse events related to the drug itself have been seen.

## Study Methods

The study results come at the end of a 24-month, placebo-controlled, dose-response clinical trial, in which patients with wet AMD were randomly assigned to receive one of three concentrations of the drug or a placebo; the therapy assignments remained unknown until the study ended. After the initial patient visit, investigators had the option to re-treat patients at six-month intervals.

Patients in the study averaged 77 years of age. There were no statistically significant differences between the therapy groups at baseline in logMAR visual acuity, total lesion size, or percentage of patients with predominantly classic lesions. The trial included 18 sites and 128 patients. Of these 128 patients, 76 completed their 12-month visit, while 55 completed their 24-month visit.

## New AMD Trial

Alcon has moved ahead with the next step to gain regulatory approval of **RETAANE™** 15 mg (anecortave acetate for depot suspension) by launching a phase III trial at more than 50 sites in the United States, Europe, Australia and Canada. Approximately 500 patients have been enrolled in this study, which

directly compares the effectiveness of **RETAANE™** 15 mg versus photodynamic therapy (PDT) using VISUDYNE\* in patients diagnosed with predominantly classic wet AMD.

### **More About AMD**

AMD is a degeneration of the macular region of the retina, the portion of the eye key to central vision. The two main types of AMD are "wet," or exudative, and "dry," or non-exudative. Although the wet form of AMD constitutes only 10 to 15 percent of all AMD cases, it is responsible for 90 percent of blindness attributable to the condition. Wet AMD has no cure, but laser surgery is often used to "seal off" the leaky vessels. As a rule, retinal damage is irreversible, so prompt treatment is essential. Generally, AMD causes vision loss around age 55, and, if untreated, can result in "social blindness" within two to three years.

### **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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\*VISUDYNE is a registered trademark of Novartis, AG.

### **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.

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