



**For immediate release**

**RETAANE® 15mg Depot Clinical Update  
Presented at Association for Research and Vision  
in Ophthalmology (ARVO) Annual Meeting**

**FORT WORTH, Texas – May 20, 2004** – Alcon, Inc. (NYSE:ACL) reviewed data on the RETAANE® 15 mg (anecortave acetate for depot suspension) phase II/III study and updated information on two new phase III studies of anecortave acetate at the Association for Vision and Research in Ophthalmology (ARVO) annual meeting in Fort Lauderdale, Fla. In addition, a physician-initiated study of RETAANE® with triamcinolone was reviewed at the meeting. RETAANE® is being developed by Alcon, Inc. as a treatment for successfully preserving the vision of patients with all forms of wet age-related macular degeneration (AMD). Alcon expects to file a New Drug Application with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2004. This filing will incorporate data from a current, multi-center, phase III clinical trial comparing RETAANE® with photodynamic therapy (PDT) in 530 patients with wet AMD. If approved, the company will begin marketing the product in the first half of 2005.

**Phase II/III Clinical Update**

Presentations at ARVO showed that RETAANE® was significantly better than placebo for preserving vision, preventing severe vision loss and inhibiting the growth of all lesion types in patients with wet AMD. At two years, 73 percent of patients treated with RETAANE® showed stable or improved vision, while only 47 percent of placebo-treated patients showed a similar vision outcome ( $p = 0.035$ ). In addition, 94 percent of patients experienced no severe vision loss after two years treatment with RETAANE®. At twelve months, 79 percent of patients treated with RETAANE® had stable or improved vision, while only 53 percent of placebo-treated patients showed a similar vision outcome.

**New Phase III Studies**

Investigator Stephen Russell, M.D., of the University of Iowa Medical School, Carver School of Medicine, presented an update on Alcon's initiation of two new phase III studies being conducted in groups of patients with advanced dry AMD who are at risk of progressing to wet AMD. The studies will evaluate the safety and efficacy of treatment every six months with anecortave acetate for depot suspension versus a sham procedure. The sham procedure imitates the procedure used to give patients the investigational drug and is a regulatory requirement for keeping the study masked as to which patients receive the drug. Anecortave acetate is the first and only drug of its pharmacological class being investigated to treat this population of at-risk AMD patients. The FDA has granted Alcon "Fast Track" designation for the study of anecortave acetate for this indication because it represents a significant unmet medical need for a serious condition.

Dr. Russell presented the study methods for the new phase III trials. The protocol states that eligible patients must have, or previously have had, wet AMD in one eye, while the other eye has no evidence of exudative AMD or geographic atrophy. Patients enrolled in the trials will be randomized 1:1:1 to administrations every six months for four years of anecortave acetate 15 mg, anecortave acetate 30 mg, or to a sham procedure. To date, approximately 170 patients have been enrolled, out of the total of 2,500 patients for the two studies.

"In the study, anecortave acetate is being evaluated for treatment in arresting the progression from dry AMD to exudative AMD in at-risk patients using an important and clinically relevant measurement criteria, the incidence of 'sight-threatening' choroidal neovascularization, or CNV," said Dr. Russell. "For this study, sight-threatening CNV is defined as fluorescein angiographic evidence of new blood vessel growth under the retina within 2500 microns of the center of the macula."

### **Physician-Initiated Trial with RETAANE<sup>®</sup> and Triamcinolone**

In addition to the phase III information presented, investigator Jason S. Slakter, M.D., of the Manhattan Eye, Ear and Throat Hospital in New York, presented study methods and initial data for a physician-initiated trial evaluating the safety and efficacy of RETAANE<sup>®</sup> 15 mg (anecortave acetate for depot suspension) and triamcinolone acetate 4mg, or a combination of both, in patients with the wet form of AMD.\* The protocol states that eligible patients must have either subfoveal occult CNV with demonstrated disease progression, or subfoveal minimally classic CNV. The first five patients in this study were treated with a combination of RETAANE<sup>®</sup> – as the first line therapy – and an intravitreal injection of triamcinolone acetate 4mg.

The results will serve as a preliminary safety assessment of the combination therapy. When the initial five patients complete the month 3 visit, another 60 patients will be enrolled in a masked study and assigned to receive either RETAANE<sup>®</sup> 15 mg (anecortave acetate for depot suspension) and a sham injection of triamcinolone acetate 4 mg, triamcinolone acetate 4mg and a sham administration of RETAANE<sup>®</sup>, or a true combination of the two drugs.

"Given the nature of these two drugs, it is possible that a combination of the agents may provide a synergistic effect, with the strong anti-permeability effect of the steroid combined with the anti-angiogenic effect of anecortave acetate," said Dr. Slakter.

### **About AMD**

Age-related macular degeneration causes damage to the macula – the light-sensitive cells at 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, as well as providing information that allows us to perceive colors; thus, allowing one to maintain independence in daily activities.

There are two types of AMD – "dry," or atrophic or non-exudative, and "wet," or exudative. Although the wet form of AMD constitutes only 10-15 percent of all AMD cases, it is responsible for 90 percent of blindness attributable to this condition. Today, wet AMD is the leading cause of blindness in industrialized nations in people over the age of 50, primarily because there is a lack of effective treatments for the disease. Currently, there is no approved treatment for dry AMD. The two currently approved treatments for wet AMD – laser photocoagulation and photodynamic therapy – are appropriate for only a percentage of patients.

### **About RETAANE<sup>®</sup>**

Anecortave acetate, the primary active ingredient in RETAANE<sup>®</sup> 15 mg (anecortave acetate for depot suspension), is an angiostatic cortisene that inhibits the abnormal growth of

blood vessels – a process scientifically known as angiogenesis. Angiostatic cortisones were derived from the steroid class and engineered to remove chemical groups responsible for unwanted glucocorticoid effects, such as the development of cataracts and elevated intraocular pressure leading to glaucoma, while preserving angiostatic (or anti-neovascular) potency.

Some investigational therapies attempt to block only one growth factor such as vascular endothelial growth factor (VEGF), thus still allowing other growth factors, such as basic fibroblast growth factor (bFGF), to signal the endothelial cells and commence the angiogenesis process. Angiostatic cortisones are able to block signals from multiple growth factors because they act downstream and independent of the initiating angiogenic stimuli thus inhibiting angiogenesis subsequent to the angiogenic stimulation.

RETAANE<sup>®</sup> is the only therapy for AMD that uses the unique delivery system of posterior juxtасcleral depot (PJD). During the procedure, RETAANE<sup>®</sup> is drawn into a blunt-tipped, curved cannula and then delivered in direct contact with the outer surface of the sclera without puncturing the eyeball. This method of delivery for RETAANE<sup>®</sup> avoids the risk of intraocular infection and retinal detachment, the most common side effects associated with frequently injecting therapeutic agents directly into the eye. RETAANE<sup>®</sup> requires less frequent administration (once every six months) compared to some other investigational angiogenesis inhibitors, which are injected into the eye as often as nine to 12 times a year. According to an independent safety panel, no clinically relevant side effects were associated with RETAANE<sup>®</sup> or the PJD procedure.

## **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. Alcon has been conducting retinal research for more than 15 years and is the world's leading provider of surgical equipment used by vitreoretinal specialists who treat patients with AMD and other retinal diseases.

# # #

\*This is a physician-initiated trial and is not being conducted by Alcon.

## **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, contact:***

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

Mary Dulle (Alcon Strategic Corporate Communications)  
817-551-8058  
[mary.dulle@alconlabs.com](mailto:mary.dulle@alconlabs.com)

Shannon Munkachy, Porter Novelli (Public Relations)  
312-856-8892  
[shannon.munkachy@porternovelli.com](mailto:shannon.munkachy@porternovelli.com)

[www.alconinc.com](http://www.alconinc.com)