



**For immediate release**

**Alcon Announces Anecortave Acetate Clinical Results**

**Hünenberg, Switzerland – October 13, 2004** – Alcon, Inc. (NYSE:ACL) has completed an initial analysis of the one-year data from its comparative study of anecortave acetate (15 mg for depot suspension) versus Visudyne® photodynamic therapy (PDT) in the treatment of wet age-related macular degeneration (AMD). In the study, the percentage of patients who maintained vision (defined as less than a three line loss in logMAR visual acuity) when treated per protocol with anecortave acetate was 45 percent, compared to 49 percent for PDT. Although anecortave acetate did not meet the primary non-inferiority endpoint of the clinical study, these overall results indicate that the two therapies are not statistically different from each other.

After analyzing the data, Alcon believes there were controllable factors that negatively impacted the overall results of the study, including drug reflux and treatment interval. Reflux occurs when a portion of the medication leaks out through the small incision in the conjunctiva during or immediately after application of the drug. The treatment interval refers to the medically reasonable timeframe during which re-administration of the drug should occur.

A preliminary analysis of the clinical data indicates that controlling for drug reflux during re-administration of anecortave acetate may provide a moderate improvement in patient outcomes.

To control reflux during administration, Alcon has initiated changes in the procedure, expanded training measures and developed a simple counter pressure device (CPD). This device has been evaluated in pre-clinical models where it was determined to be effective in controlling reflux. Based upon discussions with the U.S. Food and Drug Administration (FDA), the company has initiated a clinical pharmacokinetic study to evaluate the device. It plans to submit the results of this study to the FDA during its review of Alcon's new drug application (NDA). Furthermore, the company is incorporating this device into all current and future studies of anecortave acetate worldwide.

Safety information from this study demonstrated that no clinically relevant safety issues were observed for anecortave acetate or the posterior juxtascleral depot procedure during this course of the study. These results further confirm the favorable safety profile of the drug that has been seen in all earlier studies.

Alcon is continuing to analyze all the data from the study and plans to submit its NDA to the FDA by the end of the year. In light of the severity of the disease and the limited therapies available to treat wet AMD, Alcon believes the FDA will consider the company's entire package of efficacy and safety data in making a risk versus benefit assessment of anecortave acetate.

Alcon management will host a conference call on Friday, October 15, 2004 at 8:30am Eastern Time to discuss the results of the study. The call can be accessed at [www.alconinc.com](http://www.alconinc.com). Additionally, Alcon will present and discuss clinical data on anecortave acetate at the American Academy of Ophthalmology and retinal Sub-Specialty Meetings in New Orleans beginning on October 22, 2004.

## **About Anecortave Acetate**

Anecortave acetate is an investigational treatment for maintaining vision in patients with wet AMD. The drug is an angiostatic cortisene that inhibits the abnormal growth of blood vessels, a process scientifically known as angiogenesis. Angiostatic cortisenes are derived from the steroid class and engineered to remove chemical groups responsible for side effects, such as the development of cataracts and elevated intraocular pressure leading to glaucoma, while preserving potency against angiogenesis.

Anecortave acetate is administered with a blunt-tipped, curved cannula to deliver the drug behind the eye without puncturing the eyeball. This method of delivery avoids the risk of intraocular infection and retinal detachment, the most common side effects associated with injecting therapeutic agents directly into the eye. In addition, anecortave acetate requires less frequent dosing (once every six months) compared to some other investigational drugs, which are injected into the eye as often as nine to 12 times a year.

Alcon has conducted extensive clinical research into anecortave acetate over the last five years. The company has previously reported clinical study results from its first pivotal study, which demonstrated that 79 percent of patients treated with 15mg of anecortave acetate maintained their vision, compared to 53 percent of those who received a sham application. No clinically relevant side effects related to the medication or application procedure were reported in the study.

## **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.

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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 NDA with the FDA and the expected benefits of anecortave acetate in treating wet 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, submission and/or approval of the NDA may take longer than we expect, or we may not receive approval from the FDA; 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

817-551-8974

doug.machatton@alconlabs.com

Wes Brazell

817-551-8897

wes.brazell@alconlabs.com

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