

# **Anecortave Acetate Clinical Trial Data for Glaucoma Presented at World Congress of Glaucoma**

7/18/2007

## **Source: Business Wire**

Alcon, Inc. ([NYSE: ACL](#)) released today the three-month interim results of the first controlled clinical study of anecortave acetate administered as an anterior juxtasceral depot in the sub-Tenon's space to reduce intraocular pressure in patients with open-angle glaucoma. The data were presented in a poster at the World Glaucoma Congress in Singapore.

In this 12-month proof of concept study, 85 patients were randomly assigned to one of four arms: 3mg, 15mg or 30mg of anecortave acetate or vehicle. Prior to enrolling in the study, all patients had been diagnosed with open-angle glaucoma, had experienced glaucomatous visual field changes and had off-therapy intraocular pressures between 24 mmHg and 36 mmHg. One injection of drug or vehicle was administered to each patient and intraocular pressures were assessed at two weeks, six weeks and at month three. The study will continue with full clinical assessments through the six-month period, with safety follow-up through the conclusion of the study.

The primary conclusion of the poster was that anecortave acetate demonstrated potential for prolonged reduction of intraocular pressure in a significant percentage of patients following a single administration of the drug for all concentrations versus vehicle at month three (ANOVA,  $p$  less than 0.05). On a combined basis, 38 percent of patients in the active arms were classified as treatment successes at three months, compared to 24 percent of patients in the vehicle arm. In the highest dose (30mg), 50 percent of patients were defined as treatment successes at three months. On a combined basis, the mean intraocular pressure reduction in the three active arms at three months was 7.2 mmHg, compared to 1.4 mmHg for the vehicle arm ( $p=0.0014$ ). The poster presented data from the study on an intent to treat basis.

Additional data from the poster revealed that mean intraocular pressure declined in all three active arms and the vehicle arm at the two week point, although there were no statistical differences at this time point. However, the mean intraocular pressure decline in the three active arms was maintained at the three month time point, while mean intraocular pressure in the vehicle arm essentially returned to baseline by month three. Mean intraocular pressures at month three declined two percent for the vehicle arm compared to 15 percent for the 3mg arm ( $p=0.0536$ ), 16 percent for the 15mg arm ( $p=0.0526$ ) and 19 percent for the 30mg arm ( $p=0.0120$ ).

The poster noted that the study was designed very conservatively to ensure patient safety in a study that involved glaucoma patients with confirmed vision loss and included a vehicle group. This study used a pre-defined intraocular pressure target for continuation in the study (less than/ $\leq$ 21 mmHg), which imparted a negative bias toward demonstrating an overall beneficial treatment effect. This resulted in some patients exiting the study because their intraocular pressures rose above 21 mmHg, even though their intraocular pressures were much lower than when they entered the study. This appropriately conservative design reduced the number of patients that reached the three month endpoint, thereby preventing the achievement of the pre-defined primary endpoint of this small study.

In terms of safety, the most frequently reported adverse events included eye pain, foreign body sensation and blurred vision. Nine of the 14 reports of eye pain were associated with the injection and no patients discontinued from the study due to an adverse event. The four serious adverse events reported were stroke, irregular heart rate, uterine polyp and kidney stone, none of which were related to the study drug or procedure and there was no dose relationship evident in the safety data.

"The results of this first controlled clinical study of anecortave acetate for glaucoma are encouraging because they show that with one injection the drug works for at least three months in a significant number of glaucoma patients to lower pressure by clinically relevant amounts," said Scott Krueger, PhD, Alcon's vice president, R&D, Pharmaceutical Development. "In addition to these positive indications, we also learned more about the drug that will help us design additional studies that we believe will

become the basis for filing an anticipated new drug application with the FDA in 2009."

#### About Alcon

Alcon, Inc. is the world's leading eye care company, with sales of \$4.9 billion in 2006. Alcon, which has been dedicated to the ophthalmic industry for 60 years, researches, develops, manufactures and markets pharmaceuticals; surgical equipment and devices, contact lens care solutions and other vision care products that treat diseases, disorders and other conditions of the eye. Alcon's majority shareholder is Nestle, S.A., the world's largest food company.