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Study of Lacrisert® Dry Eye Insert
ARVO Poster: Significant Decrease in Ocular Surface Disease Index
Eye & Contact Lens Publication: Improvement in Signs and Symptoms of Dry Eye

Lawrenceville, NJ – May 3, 2010 – Aton Pharma, Inc. announced today that results from a large (n = 520) multi-center patient registry study of its Lacrisert® ophthalmic insert showed that the insert decreased ocular surface disease index (OSDI) in patients with moderate-to-severe dry eye after one month of treatment. The results will be presented as a poster this week during the 2010 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), May 2-7, Ft. Lauderdale, FL. The study results are also published online this month in the peer-reviewed *Eye & Contact Lens*.

Lacrisert (hydroxypropyl cellulose ophthalmic insert) is a preservative-free, once-daily*, sustained release prescription insert indicated for moderate to severe dry eye syndromes, that helps to retain moisture, stabilize the tear film, and lubricate the eye.

Association for Research in Vision and Ophthalmology

The poster, "Efficacy of Hydroxypropyl Cellulose Ophthalmic Inserts (HCOI) in Dry Eye Syndrome (DES) at All Levels of Severity," will be presented by Jodi Luchs, M.D., F.A.C.S., Assistant Clinical Professor of Ophthalmology and Visual Sciences, Albert Einstein College of Medicine, and Director of Cornea/External Diseases, South Shore Eye Care, Wantagh, NY (poster #557, Thursday May 6, 11:15 AM - 1:00 PM, Hall B/C).

As reported by Dr. Luchs, dry eye patients enrolled in the study were categorized according to their ocular surface disease index (OSDI) scores as severe, moderate, mild or normal. In patients who completed the study (n = 418), analysis of variance (ANOVA) showed significant differences in OSDI scores between severity groups after four weeks of treatment with Lacrisert. The largest decrease in scores was seen in the severe group (29.8% decrease, $P < .001$). Scores in the moderate group decreased by 18.9% ($P = .016$). Improvement in OSDI scores for patients in the study was over and above any improvement patients may have gained from previous dry eye therapies administered before the study. There were significant increases in OSDI scores of 83.7% ($P = .001$) and 30.2% ($P = .01$) for the normal and mild groups, respectively.

At baseline, 65.3% of patients who completed the study scored within the severe range. After 1 month of therapy, only 44% of the group scored within the severe range, shifting the distribution to normal, mild, and moderate groups. In the severe group there was a significant increase in tear film break up time (TFBUT) for both eyes ($P < .005$) compared to baseline. Blurred vision was the most commonly reported adverse effect.

"The study shows use of Lacrisert results in significant improvements for most patients in DES symptoms, in activities of daily living, and in patient quality of life," explained Dr. Luchs. "The nearly 30% improvement in OSDI scores for severe dry eye patients in four weeks suggests that the insert can meaningfully improve the ocular surface for this difficult patient group in a relatively short time."

* Some patients may require the flexibility of twice-daily dosing for optimal results.

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Eye & Contact Lens Publication

Results of the Lacrisert patient registry study were also published online in *Eye & Contact Lens* in the article “Improved Signs, Symptoms, and Quality of Life Associated With Dry Eye Syndrome: Hydroxypropyl Cellulose Ophthalmic Insert Patient Registry” (Bruce H. Koffler, M.D., Marguerite McDonald, M.D., for the LAC-07-01 Study Group). The article noted that statistically significant improvements in discomfort, burning, dryness, grittiness, stinging, and light sensitivity, as well as clinical signs of keratitis, conjunctival staining, and tear volume were observed (P<0.05). Mean OSDI scores improved by 21.3% (P<0.05). Blurred vision, affecting 8.7% of patients, was the most commonly reported adverse event.

Registry Study Methodology

A patient registry study is designed to examine a wide range of correlations and show predictive relationships, providing a rich resource of data to mine over time. In the Lacrisert study, at visit 1, patients (enrollment n = 520) were given a general dry eye evaluation, screened by slit-lamp biomicroscopy and best corrected visual acuity, and were required to fill out a questionnaire that included the ocular surface disease index (OSDI), a validated measure of quality of life. Patients were trained on the proper insertion and use of the insert. Patients were contacted by telephone on Day 3 of the study for follow up and reinstruction. At visit 2 (Week 4), patients were given a clinical evaluation and required to complete a second evaluation. Answers provided on questionnaires (scored on Likert-type scales) were used to determine changes in patient-reported outcomes such as symptoms and quality of life.

About Lacrisert

Lacrisert has been FDA-approved for use in patients with moderate to severe dry eye and available by prescription for more than two decades. Unlike artificial tear substitutes that have a residence time measured in minutes, Lacrisert provides continual lubrication and protection to the surface of the eye for all-day relief. Lacrisert acts to stabilize and thicken the pre-corneal tear film and prolong the tear film breakup time, which is usually accelerated in patients with dry eye states. Information and educational video content are available at www.lacrisert.com.

Lacrisert is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. Lacrisert is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. Lacrisert should not be used by patients who are hypersensitive to hydroxypropyl cellulose. Instructions for inserting and removing Lacrisert should be carefully followed. If improperly placed Lacrisert may result in corneal abrasion. Most adverse reactions with Lacrisert were mild and transient and included transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hypersensitivity, edema of the eyelids and hyperemia. Full prescribing information can be found at www.lacrisert.com.

About Aton Pharma, Inc.

Aton Pharma, Inc., headquartered in Lawrenceville, NJ, is a global, diversified specialty pharmaceutical company providing essential treatments for under-treated diseases. Aton's mission is to improve patient outcomes and quality of life worldwide by enhancing and expanding access and availability of medically essential therapeutics. Aton's portfolio of products, with sales in over 30 countries, focuses on ophthalmic diseases and orphan conditions. For more information, see www.atonrx.com.

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