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Large Study of Lacrisert® Dry Eye Insert Patients Experience Significant Improvement in Ocular Surface Disease and Quality of Life

Lawrenceville, NJ – May 5, 2009 – Aton Pharma, Inc. announced today that results from a large (n = 520) multi-center patient registry study of its Lacrisert® ophthalmic insert will be presented this week during the 2009 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), May 3-7, Ft. Lauderdale, FL, and later in the month at the 145th Annual Meeting of the American Ophthalmological Society (AOS), May 14 -17, Half Moon Bay, CA. Lacrisert (hydroxypropyl cellulose ophthalmic insert) is a preservative-free, once-daily*, sustained release prescription insert indicated for moderate to severe dry eye, that helps to retain moisture, stabilize the tear film, and lubricate the eye.

“This is the first major study of Lacrisert to be undertaken in more than two decades,” stated Michael G. Wells, Chief Executive Officer of Aton Pharma. “Our commitment to expanding product availability and increasing physician awareness and knowledge of Lacrisert includes gathering of key efficacy data such as through this study.”

The multicenter, 2-visit, open label, 4-week study was conducted to determine both physician and patient acceptability and ease of use of Lacrisert in adult patients with a history of dry eye syndrome. It was hypothesized that patients would experience improvements in their overall quality of life as well as in measures of dry eye signs and symptoms. 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.

Bruce H. Koffler, M.D., will present data from the study in a poster at the 2009 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), “LACRISERT® (hydroxypropyl cellulose ophthalmic insert) Significantly Improves Symptoms of Dry Eye Syndrome and Patient Quality of Life” (Bruce H. Koffler for the LAC-07-01 Study Group, poster 4660/D904, Wednesday, May 6, 1:45-3:30 PM).

As reported by Dr. Koffler, mean ocular surface disease index (OSDI) total scores for patients in the study significantly improved by more than 21% over the four weeks of the study; this was over and above any improvement patients may have gained from previous dry eye therapies administered before the study.

Treatment with Lacrisert also resulted in significant improvement in mean occurrence of discomfort in heated areas ($P < 0.0001$) and significant improvements when performing housework ($P = 0.0018$). Patients reported significant reductions in mean severity of DES symptoms ($P < 0.0001$). The most commonly reported adverse event leading to discontinuation was blurred vision, observed in 8.7% of patients.

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

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“The study shows use of Lacrisert results in significant improvements in DES symptoms, in activities of daily living, and in patient quality of life,” explained Dr. Koffler.

A second poster at the 2009 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) based on the patient registry study, “Effect of Lacrisert® on the Signs and Symptoms of Dry Eye in Contact Lens Wearers” (Wednesday, May 06, 2009, 1:45 PM - 3:30 PM, Hall B/C) will be presented by Stephen J. Curwen *et al* of Ophthalmic Research Associates (ORA). This poster focuses on a sample subset of 30 contact lens wearers with a history of dry eye.

The 30 contact lens patients reported significant improvements in dryness ($P = < 0.0001$) and grittiness ($P = 0.008$) after 4 weeks of dosing with Lacrisert when compared to baseline. Mean TFBUT increased from 2.98 to 4.08 sec. ($P < 0.0001$) and mean corneal/conjunctival staining decreased from 1.21 to 0.79 units ($P < 0.0001$). Investigators reported that 70% of subjects experienced an improvement of dry eye symptoms and 53% experienced an improvement in dry eye signs while wearing contact lenses. It was also reported that Lacrisert was longer lasting 93% of the time when compared to rewetting solutions.

“The data in this study show that Lacrisert relieves the signs and symptoms of dry eye in contact lens wearers with a history of dry eye,” concluded the ORA investigators. “Patients experienced significant improvements in tear film stability as well as ocular surface damage. Lacrisert may be longer-lasting than other available treatments.”

Marguerite McDonald, M.D., F.A.C.S., will present additional data from the study in a presentation at 145th Annual Meeting of the American Ophthalmological Society (AOS), “LACRISERT® (hydroxypropyl cellulose ophthalmic insert) Reduces the Signs and Symptoms of Dry Eye Syndrome (DES) and Improves Patient Quality of Life” (Marguerite McDonald, Gerard D’Aversa, Henry Perry, John Wittpenn and Eric Donnenfeld for the LAC-07-01 Study Group, Saturday, May 16).

Dr. McDonald reports that patients experienced significant improvements in discomfort, burning, dryness, grittiness, stinging, and light sensitivity ($P < 0.0001$) after 4 weeks of treatment with Lacrisert. Overall, 57% of subjects experienced an improvement of dry eye symptoms and 54% in clinical signs (including Schirmers Test, conjunctival staining and TFBUT).

“The study shows Lacrisert significantly reduces symptoms and clinical signs of moderate to severe dry eye, which is borne out by my own clinical experience as well,” stated Dr. McDonald.

Registry Study Methodology

In the Lacrisert study, at visit 1, patients ($n = 520$) 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.

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. Lacrisert should not be used by patients who are hypersensitive to hydroxypropyl cellulose. If improperly placed, Lacrisert may result in corneal abrasion.

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 ten products, with sales in over 30 countries, focuses on ophthalmic diseases, orphan conditions and acute care hospital products. For more information, see www.atonrx.com.

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