



Alimera Sciences Submits Iluvien(R) NDA to the FDA for the Treatment of Diabetic Macular Edema

ATLANTA, Jun 29, 2010 (GlobeNewswire via COMTEX News Network) -- Alimera Sciences, Inc., (Nasdaq:ALIM), ("Alimera"), a biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals, has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Iluvien(R), (flucocinolone acetonide intravitreal insert), its investigational, sustained drug delivery system releasing sub-microgram levels of fluocinolone acetonide for the treatment of diabetic macular edema (DME). In the submission, Alimera requested priority review, which, if granted, could result in an action letter from the FDA in the fourth quarter of 2010.

"This is a significant milestone for all of us at Alimera, and represents a major advance toward a rapid and sustained visual acuity benefit for DME sufferers," said Dan Myers, president and CEO of Alimera, adding, "We believe that Iluvien(R), if approved, will provide a needed alternative to the multiple injections of corticosteroids and anti-VEGF therapies used off-label for extended efficacy in DME. We believe this would be the first ophthalmic drug therapy to be approved for DME and the only DME treatment that works in terms of years, not months."

Alimera is currently conducting two Phase 3 pivotal clinical trials (collectively known as the FAME Study) for Iluvien(R) involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien(R) with two doses, a high and low dose, for the treatment of DME. The primary efficacy endpoint for the FAME Study is the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups. The study will conclude later this year with the final patient visits at the three-year data point. The 24-month clinical readout from the study was completed and announced in December 2009.

This NDA submission includes the 24-month low dose data from the FAME Study. Alimera plans to follow this NDA submission with registration filings in certain European countries and Canada in the near future.

About DME

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a 10-year period approximately 19% of diabetics studied were diagnosed with DME. Based on this study and the current U.S. diabetic population, Alimera estimates that there will be an incidence of approximately 340,000 cases of DME annually in the United States. As the population of people with diabetes increases, Alimera expects the annual incidence of diagnosed DME to increase, as well.

About Iluvien(R)

Iluvien(R) is an investigative, extended release intravitreal insert that Alimera is developing for the treatment of DME. Each Iluvien(R) insert is designed to provide a therapeutic effect of up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FA). Iluvien(R) is inserted in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. The insertion device employs a 25-gauge needle, which allows for a self-sealing wound.

About Alimera Sciences, Inc.

Alimera Sciences, Inc., based in Alpharetta, Georgia, is a biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. Presently the Company is focused on diseases affecting the back of the eye, or retina. Its advanced product candidate, Iluvien(R), is an intravitreal insert containing fluocinolone acetonide, a non-proprietary corticosteroid with demonstrated efficacy in the treatment of ocular disease. Iluvien (R) is in development for the treatment of diabetic macular edema (DME), a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness.

Forward Looking Statements

This press release contains "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, regarding, among other things, Alimera's future results of operations and financial position, business strategy and plans and objectives of management for Alimera's future operations. Words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "likely," "will," "would," "could," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The events and circumstances reflected in Alimera's forward-looking statements may not occur and actual results could differ materially from those projected in its forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to, delay in or failure to obtain regulatory approval of Alimera's product candidates, uncertainty as to Alimera's ability to commercialize, and market acceptance of, its product candidates, the extent of government regulations, uncertainty as to relationship between the benefits of Alimera's product candidates and the risks of their side-effect profiles, dependence on third-party manufacturers to manufacture Alimera's product candidates in sufficient quantities and quality, uncertainty of clinical trial results, limited sales and marketing infrastructure, as well as other factors discussed in Alimera's Securities and Exchange Commission filings, including Alimera's quarterly report on Form 10-Q for the quarter ended March 31, 2010 filed with the Securities and Exchange Commission.

All forward-looking statements contained in this press release are expressly qualified by the above paragraph in their entirety. These forward-looking statements speak only as of the date of this press release (unless another date is indicated). Alimera undertakes no obligation, and specifically declines any obligation, to publicly update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

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SOURCE: Alimera Sciences, Inc.

CONTACT: Fleishman-Hillard for Alimera Sciences
Katie Brazel
404-739-0150
katie.brazel@fleishman.com

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