First Oral Drug for Uveitis Reduces Both Inflammation and Recurrence Rate in Potentially Blinding Eye Disease, Reports Lux Biosciences

-- LX211 Phase 3 Data from LUMINATE Trials Presented at ARVO--

-- If Approved, LX211 Would Address an Important Unmet Medical Need for Patients with Uveitis--

Fort Lauderdale, FL (May 4, 2009): Uveitis, or inflammation within the eye, is a group of diseases responsible for years of visual loss roughly comparable to that caused by diabetes. Now, results from a pioneering international Phase 3 program in uveitis, the LUMINATE trials sponsored by Lux Biosciences, demonstrate the ability of LX211 (LUVENIQ™, voclosporin oral capsule) to significantly improve this chronic eye inflammation. Additionally, in patients who are discontinuing potentially toxic medications for uveitis, such as the corticosteroid prednisone, LX211 actively reduces the rate of inflammatory exacerbations by 50% at six months, compared to placebo. The study results also show a safety profile for LX211 at the 0.4 mg/kg bid dose that suggests the experimental drug would be suitable for chronic use as the first oral treatment for this sight-threatening inflammatory eye disease, while also providing a means to greatly reduce the serious health risks associated with long-term corticosteroid use. LX211 is a novel and proprietary next-generation calcineurin inhibitor that Lux Biosciences is developing for ophthalmic uses.

Dr. James T. Rosenbaum, M.D., Professor of Ophthalmology, Medicine and Cell Biology and Vice-Chair of the Department of Ophthalmology of the Casey Eye Institute – Oregon Health Sciences University (OHSU), represented the LUMINATE Investigator Network in presenting the Phase 3 LUMINATE program results for the first time at the 2009 annual meeting of the Association for Research in Vision and Ophthalmology (ARVO). The LUMINATE program, consisting of three randomized, double-masked, dose-ranging and placebo-controlled trials that enrolled a total of 558 patients at 56 sites in 7 countries (United States, Canada, United Kingdom, France, Germany, Austria and India), is the largest clinical program ever conducted in uveitis.

“Uveitis, a term used to classify a group of autoimmune diseases characterized by chronic inflammation of the eye, is the 4th leading cause of blindness and often affects patients under the age of 40, but the disease remains frequently mistreated,” commented Dr. Rosenbaum. “Uveitis has many causes and experts often disagree about what constitutes successful treatment. Accordingly, no pharmaceutical company previously has attempted to demonstrate that an oral medication can successfully treat uveitis, and there are currently no FDA-approved oral medications for this condition. Treating physicians often prescribe corticosteroids, which are burdened with a variety of serious systemic side effects when given orally. Even if applied as drops to the eye, corticosteroids can cause cataract formation and glaucoma. Based on the results of the LUMINATE trial program, LX211 appears to offer a therapeutic and safety profile that would meet the critical need for an oral medication for uveitis. LX211 is not a corticosteroid, but allows the reduced use of corticosteroids like prednisone, which in turn reduces the serious side-effects associated with those drugs.”

Dr. Rosenbaum noted that a poster presentation at ARVO from a survey of U.S. ophthalmologists and rheumatologists from 27 states, presented by researchers from the Wilmer Eye Institute of Johns Hopkins

University, Baltimore, found that the dose of oral corticosteroids used commonly to keep chronic inflammation within the eye under control is in the range of 25 mg/day. This compares to a recommended chronic dose by the uveitis community of 10 mg/day or less. Of additional note, patients enrolled in the LX211-02 protocol, which evaluated the use of LX-211 in subjects with treated but quiescent disease, received doses of corticosteroids that were more than 50% higher than this recommendation. It is well documented that systemic steroids at doses above 10 mg/day cause a myriad of adverse effects, such as osteoporosis, resulting in increased risk for hip or spinal fractures, and metabolic disturbances including obesity, heart disease, and diabetes. Mood disturbances are also associated with chronic corticosteroid use.

“The tapering of systemic corticosteroids to 5 mg or less per day, as implemented successfully in the LUMINATE studies, provides for additional safety from steroid morbidities,” Dr. Rosenbaum commented.

“We are pleased with the demonstrated clinical effect of LX211 (Luveniq™) in uveitis, coupled with what appears to be an acceptable side effect profile while reducing the need for systemic corticosteroid to half of the current guideline recommendation,” commented Ulrich Grau, Ph.D., Lux Biosciences’ President and Chief Executive Officer. “We’re now pursuing regulatory filings, and if approved for commercialization by the appropriate regulatory agencies, LX211 would become the first agent in this class available in the United States and most other markets for the treatment of uveitis.”

For more information on uveitis, its incidence, and how the disease is currently treated, please see http://www.luxbio.com/Uveitis Backgrounder.pdf

Overview of LUMINATE Trial Results

The LUMINATE program consists of three protocols that included 218 patients with active non-infectious uveitis with posterior (behind the lens of the eye) manifestation of the disease (LX211-01); 232 patients with clinically quiescent disease (LX211-02); and 108 patients with active uveitis with anterior (front of the eye) manifestation of the disease (LX211-03). Data from these trials showed:

- Of the three doses studied, the 0.4 mg/kg BID dose had the most acceptable safety profile relative to effect on the disease. The adverse effects on the kidney (8.2% of subjects with decrease from baseline by ≥30% in glomerular filtration rate vs. 4.1 % in placebo) and blood pressure (mean increase in systolic BP by 6 mm Hg) will require monitoring, but were overall moderate and manageable. Triglycerides and cholesterol were not elevated and had no negative impact on the cardiovascular safety profile. Hair growth (hirsutism) was observed in 5% of patients. Otherwise the safety profile was similar to placebo.
- In study LX211-01 the 0.4 mg/kg BID dose fully met the primary endpoint of superiority to placebo at both weeks 16 (p=0.008) and week 24 (p=0.027) for mean change from baseline in vitreous haze, a validated measure of inflammation of the posterior segment of the eye. The magnitude of the effect was >1 step change from baseline, demonstrating a clinically relevant benefit.
- In study LX211-02 the 0.4 mg/kg BID dose showed a reduction by 50% vs. placebo in rate of recurrence of inflammation at 6 months using a pre-specified analysis that

accounted for data censoring due to non-efficacy-related discontinuations. This reduction was statistically significant (p=0.045), thus confirming the positive results from LX211-01.

- In study LX211-03, treated patients reduced the cellular response in the front of the eye from an average of more than 25 white blood cells per high power microscopic field to an average of 6 to 10 cells per high power field. However, placebo-treated patients also improved in this study and it was therefore not possible to show that LX211 was effective for this rare subset of uveitis patients, those with refractory disease in the anterior portion of the eye.

The LUMINATE program was conducted under the sponsorship of Lux Biosciences.

About Lux Biosciences

Lux Biosciences, Inc. is a privately held biotechnology company focused on ophthalmic diseases. The company has a staged product portfolio of potentially first-in-class therapies distinguished by their short-term path to commercialization and potential to generate high revenue growth. The portfolio includes:

- Two Phase 3 clinical-stage projects including: i) LUVENIQ™, the oral formulation of a next-generation calcineurin inhibitor (voclosporin) developed as steroid-sparing therapy for the treatment of sight-threatening non-infectious uveitis, and ii) LUMITECT™, a silicone matrix ocular (episcleral) implant that steadily releases therapeutic doses of cyclosporine A locally to the eye for the prevention of rejection in corneal transplant recipients. Both the LUMINATE pivotal clinical program for LUVENIQ for the treatment of uveitis, as well as the LUCIDA pivotal clinical program with LUMITECT™, for the prevention of corneal transplant rejection were initiated in early 2007 and include sites in North America, Europe and India. Enrollment in the LUMINATE program was completed in June 2008. Enrollment in the LUCIDA program was completed in March 2009. Lux Biosciences has licensed voclosporin from Isotechnika, Inc. for development in ophthalmic indications.
- LX214 is a novel topical eye drop formulation that entered human clinical testing for dry eye syndrome in February 2009. Based on Lux's proprietary next-generation calcineurin inhibitor, LX214 is targeted towards other chronic inflammatory diseases of the eye, most notably dry eye syndrome, blepharitis and atopic keratoconjunctivitis.
- Several earlier stage projects based on proprietary product-enabling bio-erodible polymer technologies that facilitate targeted and sustained delivery of molecules to the eye.

For more information on Lux Biosciences, please visit the company's website at http://www.luxbio.com.

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