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Lux Biosciences Reports Positive Results from LUMINATE Phase 3 Program of LX211 (LUVENIQ™) in Uveitis

JERSEY CITY, N.J. (March 26, 2009) – Lux Biosciences, Inc. today reported the results from the three phase 3 LUMINATE trials of the company's LX211 (LUVENIQ™, voclosporin oral capsule) drug candidate for the treatment of uveitis. The data show a positive effect on ocular inflammation and a safety profile consistent with the expected use of LX211 in this indication. Following full analysis of the data, the results of the LUMINATE clinical trials will be submitted for publication and presented at upcoming conferences. In parallel, the company will be preparing submissions for approval.

"The available results from the LUMINATE program demonstrate that LUVENIQ, if approved, can play a significant role in the treatment of inflammation in certain forms of sight-threatening uveitis," said Eddy Anglade, M.D., Lux Biosciences' Chief Medical Officer. "A significant unmet therapeutic need exists for an approved agent which is not a corticosteroid and allows sparing of those drugs to reduce their associated, serious side effects."

The three randomized, double-masked, dose-ranging and placebo-controlled trials comprising the LUMINATE Program, the largest clinical program ever conducted in uveitis, enrolled 558 patients at 56 sites in 7 countries (United States, Canada, United Kingdom, France, Germany, Austria and India). The trials included 218 patients with active non-infectious uveitis with posterior manifestation of the disease (LX211-01), 232 patients with clinically quiescent disease (LX211-02), and 108 patients with active uveitis with anterior manifestation of the disease (LX211-03). The key results in the LUMINATE trials were:

- Overall, of the 3 doses studied, the 0.4 mg/kg BID dose had the most acceptable safety profile relative to effect on the disease. Isotechnika, Inc. previously reported that 0.4 mg/kg BID demonstrated both efficacy and an acceptable safety profile in their clinical trial of voclosporin in plaque psoriasis; the maintenance dose for the anticipated use in kidney transplantation is also similar to this dose.
- 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 ($p=0.04$) 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, 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. The study did not meet the primary analysis endpoint of all-cause therapeutic failure at 6 months, as the drug effect on inflammation was diluted by discontinuations that were unrelated to inflammation. However, the reduction in inflammation vs. placebo by 50% was statistically significant ($p=0.046$), thus confirming the positive results from LX211-01.
- In study LX211-03 the efficacy of the LX211 dose groups and placebo did not separate during the steroid taper; all showed an improvement by >1 step mean reduction from baseline in anterior chamber cells, a validated measure of inflammation in the anterior segment of the eye. This study, which is not critical for approval and was added to encompass a sub-set of patients affected by anterior chamber disease turned out to be underpowered owing to greater than expected variability.

The integrated safety profile of 0.4 mg/kg BID LX211 in the LUMINATE trials suggests that it would be suitable for chronic use in this high medical need indication. Of particular interest were the relatively small effects of LX211 0.4 mg/kg BID on renal function, an area of concern for first-generation calcineurin inhibitors. The proportion of subjects experiencing a confirmed rate of decrease in estimated glomerular filtration rate (eGFR) by ≥30% was 8.2% in the 0.4 mg/kg BID dose group vs. 2.7% in the placebo group. Patients experienced a mean increase in systolic blood pressure by study-end over baseline of 6 mm Hg. However, most of these patients were successfully controlled with medication and only 1.3% discontinued therapy due to hypertension. Other adverse events typical of the calcineurin inhibitor class, in particular diabetes, elevation of lipids, hypomagnesemia, and tremor, were not observed in the LUMINATE studies. Other more frequently observed adverse events included headache, diarrhea and infections, which were similar in incidence to placebo. In terms of ocular safety there was no apparent effect on intraocular pressure, cataract formation or endothelial cell density.

Ulrich Grau, Ph.D., Lux Biosciences' President and Chief Executive Officer, said, "Based on the available data from the LUMINATE pivotal trial program, we plan to engage in discussions with several regulatory agencies and plan regulatory filings of LUVENIQ in the near future. We are gratified by what appears to be a robust clinical effect of LUVENIQ coupled with an acceptable side effect profile."

LX211 is designed for use as an oral immune-modulatory agent to treat the forms of non-infectious uveitis that require systemic treatment, including posterior, intermediate and panuveitis, allowing for tapering of systemic corticosteroids to 5 mg or less per day. The mean age of these patients is approximately 40 years and uveitis is the 4th leading cause of blindness; hence, the burden of disease is relatively higher than for age-related ophthalmic diseases, and the medical need for effective treatments is striking.

LX211 (voclosporin oral capsule) is a novel and proprietary next-generation calcineurin inhibitor licensed by Lux Biosciences for ophthalmic use from Isotechnika, Inc. (Edmonton, Canada). If approved for commercialization by regulatory agencies, LX211 would be the first corticosteroid-sparing agent available in the United States and most other markets for the treatment of uveitis.

About Uveitis

Uveitis is an autoimmune disease characterized by chronic inflammation of the eye. Uveitis is an under-diagnosed and under-recognized medical condition that causes vision impairment, ocular pain, and loss of vision. Experts estimate that 10% of new cases of blindness in the United States result from this disease. Approximately 300,000 people suffer from uveitis in the United States alone. The only therapeutic class approved by the FDA for treatment of uveitis is corticosteroids, which are burdened with multiple side effects, such as osteoporosis, hyperglycemia, hypercholesterolemia, hypertension, mood disturbances, and if applied chronically to the eye, cataract formation and glaucoma.

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.
- LX214 is a novel topical eye drop formulation that entered human clinical testing for dry eye syndrome in Q1 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 www.luxbio.com.

Forward-Looking Statements

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This press release may contain forward-looking statements, including Lux Bioscience's belief as to the medical and commercial potential of its product candidates, Lux Bioscience's plans to pursue business and regulatory strategy, and Lux Bioscience's expectations regarding actions and decisions solely within the control and purview of other parties. These forward-looking statements involve important known and unknown risks and uncertainties, which could cause actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the exercise of discretion by regulatory agencies and other parties, the availability to Lux Biosciences of funds and resources to pursue research and development projects, the performance of activities and generation of scientific data by parties other than Lux Biosciences, the ability of Lux Biosciences to economically manufacture and commercialize its products once approved, acceptance by the medical community of Lux Biosciences' products once approved and the availability of alternative therapeutic agents, approval for reimbursement by third-party payors of Lux Biosciences' products once approved, the success and timely completion of clinical trials and other scientific studies, the ability of Lux Biosciences and its licensors to defend its and their patents from infringement by third parties, and the risk that such patents may be subsequently shown to be invalid or that the practice of such patents may infringe the patents of others. Further, Lux Biosciences disclaims any undertaking to issue further press releases or otherwise advice about changes to these beliefs, plans and expectations.

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