Lux Biosciences Files for LUVENIQ™ Approval in US and Europe for Noninfectious Uveitis

JERSEY CITY, N.J., February 4, 2010 -- Lux Biosciences, Inc. today announced its submission of simultaneous regulatory filings to both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) seeking marketing approval for its investigational drug LUVENIQ™ (LX211; oral voclosporin) for the treatment of noninfectious uveitis involving the intermediate or posterior segments of the eye. Efficacy of LX211 in support of the indication sought was demonstrated in two controlled, randomized, multi-center trials including data from 450 patients at 56 sites in 7 countries. The safety data include a total of 2,110 subjects who received voclosporin during its clinical development in uveitis and psoriasis, about 500 of whom were treated for >36 weeks and about 200 for >52 weeks. LX211 had previously received orphan drug status from FDA and EMA, and fast track status from FDA. Based on the latter, Lux Biosciences has requested priority review from FDA.

“The results seen in the LUMINATE clinical trial program, the largest completed to date in non-infectious uveitis, support our belief that LX211 has the potential to significantly advance the treatment of this blinding disease,” said Ulrich Grau, Ph.D., Lux Biosciences’ President and Chief Executive Officer. “This is the first regulatory filing of voclosporin in any indication, in any country, which made this submission a complex task. It incorporates the research and development undertaken by our collaboration partner Isotechnika over more than a decade, and that of Lux Biosciences over the last 3 ½ years. Simultaneous filings of both a U.S. New Drug Application (NDA) and a European Marketing Authorization Application (MAA) for LX211 represent a major milestone for Lux Biosciences.”

He added, “I wish to thank all of the Lux Biosciences employees, our partner Isotechnika, investigators, patients, contractors and advisors who contributed to the development program and made these on-time filings possible. I am not aware of a company of our small size having accomplished a submission of this magnitude for a new molecular entity simultaneously in the United States and Europe. It is a tribute to our networked approach to development, whereby a large team led and managed by a small core group was able to complete a major international drug development program in record time.”

Results from the LUMINATE program, submitted in support of both the U.S. and European marketing applications, showed that LX211 at the recommended dose of 0.4 mg/kg twice daily provided clinically meaningful efficacy and enabled preservation of vision in treated patients, a critical patient benefit. Study LX211-01, in subjects with uncontrolled uveitis, showed LX211 to rapidly reduce inflammation in subjects with moderately severe disease, either alone or in combination with systemic corticosteroids. Subjects receiving LX211 experienced a 50% reduction in mean vitreous haze as compared to 29% in placebo-treated subjects. The proportion of subjects demonstrating an improvement of at least 2 grades in vitreous haze or a grade of ≤1+ for the study eye at last visit was 64% in the LX211 group as compared to 46% in the placebo group. Moreover, treatment with LX211 permitted the withdrawal of

immunosuppressive therapy and the use of 5 mg/day or less of prednisone.

Study LX211-02 demonstrated the efficacy of LX211 in subjects whose disease was clinically quiescent at the time of enrollment. Nearly 90% of the patients in this study were receiving one or more forms of systemic immunosuppression prior to randomization. In this study, treatment with LX211 resulted in a 50% reduction in the rate of inflammatory exacerbations at the 26-week primary endpoint compared to those receiving placebo; a similar result was observed at 50 weeks. This indicates that relative to placebo, a patient's exposure to ocular inflammatory exacerbations that lead to loss of vision and to potentially damaging exposure to high rescue doses of steroids is approximately cut in half when LX211 therapy is administered at the clinically effective dose. Treatment with LX211 also enabled the concomitant withdrawal of immunosuppressive therapy and allowed the reduction of systemic corticosteroids to 5 mg/day or less, as well as the complete elimination of topical corticosteroid therapy.

The most common adverse events (>5%) occurring at a rate higher in treated patients than those receiving placebo, regardless of whether they were drug related or not, were hypertension, decreased renal function, diarrhea, pyrexia and arthralgia. All cases of reported hypertension were treatable, and all cases of decreased renal function were reversible. The most commonly observed infections reported were nasopharyngitis, urinary tract infection, and upper respiratory infections, but no opportunistic infections were observed. Adverse event risks in general did not appear to be increased with longer-term use. Additionally, no meaningful signals of more serious treatment effects were observed, even at a lesser frequency, in either study.

"LX211 at the recommended dose of 0.4 mg/kg twice daily, possesses a favorable benefit-risk profile for the treatment of noninfectious uveitis involving the intermediate or posterior segments of the eye," said Eddy Anglade, M.D., Lux Biosciences Chief Medical Officer. "If approved, LX211 would offer physicians a valuable oral treatment option capable of modifying the course of uveitis by effectively controlling the inflammation that characterizes this potentially blinding eye disease and significantly reducing its rate of recurrence. Avoiding inflammatory exacerbations that result in ocular morbidity and the loss of vision, coupled with avoidance of steroid-induced morbidities, is central to the management of patients afflicted with uveitis. LX211 has been shown to provide a means to attain these therapeutic goals in a disease that requires effective intervention and for which current therapeutic options are limited and deficient."

About LUVENIQ™

LUVENIQ (LX211) is the oral form of a next-generation calcineurin inhibitor, voclosporin. Like other molecules of this class, the compound reversibly inhibits immunocompetent lymphocytes, particularly T-lymphocytes, and it also inhibits lymphokine production and release. Lux Biosciences has exclusive worldwide rights to voclosporin for ophthalmic use and is cooperating with the team at Isotechnika

Pharma who discovered the molecule and develop it in psoriasis and organ transplantation.

About Uveitis

Uveitis, which represents a group of serious inflammatory eye conditions, is inevitably associated with either severe vision loss or substantial morbidity from steroid use. Non-infectious uveitis involving the posterior segment of the eye is a leading cause of vision loss and long-term disability and the fourth leading cause of legal blindness in the industrialized world. As the majority of uveitis patients are first diagnosed at ages under 40 years, the socio-economic burden of this disease is higher than that of other serious ocular conditions such as AMD and diabetic macular edema.

About Lux Biosciences

Lux Biosciences, Inc. is a privately held biotechnology company focused on the treatment of ophthalmic diseases. Its submission stage project LUVENIQ (LX211) is the oral formulation of a next-generation calcineurin inhibitor (voclosporin) for which positive phase 3 data have been obtained for the treatment of sight-threatening non-infectious uveitis. The company has several earlier stage projects based on its mixed nanomicellar ocular formulation technology, and based on its 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.

Lux Biosciences cautionary statement regarding forward-looking statements

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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