Potential of Lux Biosciences' LUVENIQ (LX211) as First Disease Modifying Treatment for Sight-Threatening Non-Infectious Uveitis Highlighted at American Academy of Ophthalmology

Lux Biosciences Preparing to File for US and European Approval

JERSEY CITY, N.J.--(BUSINESS WIRE)-- An experimental drug, LX211 (LUVENIQ™; oral voclosporin)**,** may become the first approved oral treatment capable of modifying the course of uveitis, a group of serious eye conditions inevitably associated with either severe vision loss or substantial morbidity from steroid use. Results of international Phase 2/3 clinical trials conducted by Lux Biosciences, to be the subject of two podium presentations at the American Association of Ophthalmology (AAO) meeting and of a presentation at the satellite meeting of the American Uveitis Society (AUS) in San Francisco, October 24-27, highlight the ability of LX211 to control the inflammation that characterizes this potentially blinding eye disease and significantly reduce its rate of recurrence. Lux Biosciences plans to file an NDA and MAA for marketing approvals around year-end 2009 and early 2010 in the United States and Europe, respectively.

"The LX211-02 study was a double-masked, placebo-controlled, dose-ranging study that included 232 patients at 57 centers in North America, Europe and India with clinically inactive uveitis involving any location within the eye," said Bahram Bodaghi, M.D., Ph.D., Pitié Salpétrière Hospital Paris, France, who will present the study results on Monday October 26 at 8:50 am PT. "Results of this trial showed that LX211 was able to reduce recurrence of inflammation by 50% over placebo at the 0.4 mg/kg twice daily dose ($p<0.05$) and may therefore effectively increase the interval between inflammatory relapses to 24 months compared to 10 months with placebo."

"Given that inflammatory exacerbation is a direct trigger of vision loss," Prof. Bodaghi commented, "this result for LX211 is impressive. In addition to a marked reduction in recurrence of inflammation, visual acuity was preserved in this study. Moreover, these results suggest the potential for disease modification whereby treatment with LX211 alters the course of the disease leading ultimately to improved outcomes in this difficult-to-treat condition."

Results of the LX211-01 study, which investigated LX211 in 218 patients with active, sight-threatening uveitis affecting the posterior segment of the eye, will also be presented at AAO on Monday October 26 at 9:00 am PT by clinical investigator Quan D. Nguyen, M.D., of the Wilmer Eye Institute at The Johns Hopkins University, Baltimore, MD. "In this study, also a double-masked, placebo-controlled, dose-ranging trial conducted in North America, Europe and India, control of inflammation was evaluated by means of change in vitreous haze at weeks 16 and 24. Results

showed the LX211 presumed label dose of 0.4 mg/kg twice daily to be statistically significantly superior to placebo at both time points. Preservation of vision was also demonstrated in this study."

In explaining the overall clinical benefit, C. Stephen Foster, MD, President, Massachusetts Eye Research and Surgery Institution (MERSI), highlighted the ability of LX211 to control inflammation and to significantly delay recurrence of inflammatory exacerbation compared to the control group. Moreover, this result was achieved while successfully reducing corticosteroids to 5 mg/day or less. "Therapy with LUVENIQ conforms to the 2000 uveitis treatment guidelines, and is supported by randomized clinical trials that offer the highest level of evidence-based support. Once approved, LUVENIQ would be the only uveitis therapy so rated and thus, one that should always be offered," Dr. Foster stated in his presentation to the AUS on Sunday October 25 at 8:00 pm PT.

Treatment with LX211 was overall well tolerated at the twice-daily 0.4 mg/kg dose, demonstrating a safety profile that appears suitable for chronic use. Adverse effects on renal function (8.2% of subjects with decrease from baseline of ≥30% in glomerular filtration rate vs. 4.1 % in placebo) and blood pressure (mean increase in systolic BP by 6 mm Hg) were moderate and manageable. Abnormal hair growth (hirsutism) was observed in 5% of patients. Otherwise the safety profile was similar to placebo, and triglycerides and cholesterol were not elevated.

"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," said Ulrich Grau, Ph.D., Lux Biosciences' President and Chief Executive Officer. "As the majority of patients are first diagnosed at ages under 40 years, the socio-economic burden of uveitis is higher than that of other serious ocular conditions such as AMD and diabetic macular edema. The results from these clinical trials suggest that LX211 may have the potential to significantly change the face of uveitis therapy, based on its ability to modify the course of the disease. This is analogous to the advent of disease-modifying anti-rheumatic drugs (DMARD's) and their impact on the course of rheumatoid arthritis."

For more information about uveitis, its incidence, and how the disease is currently treated, please see http://www.luxbio.com/Uveitis%20Backgrounder.pdf

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 recently been obtained for the treatment of sight-threatening non-infectious uveitis. Lux Biosciences is collaborating with the team at Isotechnika Pharma who invented the molecule and develops it for other indications. 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 http://www.luxbio.com.

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