



Lux Biosciences Reports Phase 1 Safety Results and Open Label Efficacy Results for LX214, a Potential Best-in-Class Treatment for Dry Eye

JERSEY CITY, NJ (Sept 23, 2009): Lux Biosciences, Inc. a privately held biotechnology company focused on the treatment of ophthalmic diseases, today announced results from a Phase 1 human safety and an open-label pilot efficacy study of the company's potential best-in-class therapy for dry eye, LX214 (topical mixed nanomicellar formulation of voclosporin). Randomized, double-masked, placebo-controlled data from 30 healthy volunteers showed LX214 to be well tolerated at the two doses (0.02% and 0.2%) studied, with safety and tolerability measurements (pain, burning, reddening, photophobia, foreign body sensation and others) indistinguishable from placebo.

An additional cohort of five patients with severe dry eye syndrome was treated with LX214 in both eyes twice a day for 14 days at the target 0.2% concentration. Data from these patients confirmed that systemic exposure to voclosporin was very low and below the threshold level where measurement of voclosporin blood concentrations would be required in future studies. Signs and symptoms of disease were also assessed in this cohort of patients. Despite the small sample size and short duration of treatment, clinically meaningful improvements were noted in both signs (tear production) and symptoms (OSDI index) at both 7 and 14 days, a trend that bodes well for longer term, controlled studies to follow.

"The benign safety and tolerability results in humans demonstrated in both these trials confirm the positive profile exhibited by LX214 in preclinical studies, which showed this drug candidate to establish therapeutic levels in relevant ocular tissues and to be non-irritating when applied topically to the eye," said Eddy Anglade, M.D., Lux Biosciences' Chief Medical Officer. "Moreover, even though the 14 day results in severe dry eye patients were based on a small, uncontrolled sample, they presented quite encouraging indicators of efficacy."

LX214, developed in cooperation with Ashim Mitra, Ph.D., University of Missouri Curator's Professor of Pharmacy and Director of Translational Research at UMKC School of Medicine School of Pharmacy, University of Missouri-Kansas City, is a proprietary formulation of Lux Biosciences' next generation calcineurin inhibitor, voclosporin. Utilizing voclosporin and Lux's proprietary mixed nanomicellar formulation technology, LX214 establishes high levels of drug for 24 hours in relevant ocular tissues following a single administration, including the lacrimal gland and submandibular lymph nodes, suggesting that LX214 may be efficacious and suitable for once daily dosing.

"We are very pleased by the results of this initial human study, which supports the potential of LX214 to become a best-in-class therapy in dry eye, an indication that affects as many as 10 million patients in North America and Europe," said Ulrich Grau, Ph.D., President and Chief Executive Officer of Lux Biosciences. "Lux has been able to transform voclosporin, a molecule with a mode of action that is applicable to a variety of ophthalmic diseases, into a pipeline of tailored, proprietary products that maximizes the value of this asset. LX214, the topical mixed nanomicellar formulation of voclosporin, was

developed and advanced into clinical testing in less than two years, and we view it as the “crown jewel” in the earlier stage Lux Biosciences pipeline. In addition, the mixed nanomicellar technology has now been validated in humans adding a highly valuable proprietary platform to the Lux portfolio.”

About Lux Biosciences

Lux Biosciences, Inc. is a privately held biotechnology company focused on the treatment of ophthalmic diseases. The company has a staged product portfolio that includes potential first-in-class therapies with a short-term path to commercialization and high revenue potential. The portfolio includes:

- A submission-stage project, LUVENIQ™, 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. The 0.4 mg/kg BID dose was superior to placebo in reducing active posterior segment inflammation at both Week 16 ($p < 0.01$) and Week 24 ($p < 0.05$). In a second study, LUVENIQ at the 0.4 mg/kg BID dose demonstrated a 50% greater reduction in inflammatory exacerbation rate at 6 months than placebo ($p < 0.05$) in subjects with medically controlled posterior segment disease. Increased blood pressure, decreased renal function and hirsutism were the adverse events observed at a rate of approximately 5% increment over placebo, overall giving rise to a safety profile that appears conducive for chronic use. Lux Biosciences is collaborating with the team at Isotechnika Pharma who invented the molecule and develops it for other indications.
- A Phase 3 clinical-stage project, LUMITECT™, a silicone matrix ocular (episcleral) implant that continuously elutes cyclosporine A locally to the eye for the prevention of rejection in high risk corneal transplantation. The LUCIDA pivotal clinical program with LUMITECT™, for the prevention of corneal transplant rejection completed patient recruitment in March 2009 and first results are expected in late 2009.
- LX214, an innovative topical formulation for dry eye syndrome that has completed Phase 1 clinical testing. Utilizing voclosporin and Lux’s proprietary topical mixed nanomicellar formulation technology, LX214 establishes high levels of drug concentration in relevant ocular tissues and is well tolerated in both animals and human volunteers. In addition to dry eye, LX214 has potential value in other chronic inflammatory diseases of the eye, such as 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>.

Forward-Looking Statements

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