

Potential best in class for dry eye

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LX214, a topical mixed nanomicellar formulation of voclosporin, has completed its Phase 1 human safety and an open-label pilot efficacy study and is being heralded by its maker Lux Biosciences as a promising treatment for dry eye.

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.

"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, MD, 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."