



Kala Pharmaceuticals Co-founder Publishes Data on Novel Therapeutic Approach to Overcome Mucosal Barrier for Prevention of Herpes Simplex Virus-2 Infection

Results in *Science Translational Medicine* Demonstrate Ability of Mucosal-Penetrating Products (MPPs) to Achieve Retained Drug Levels and Enhanced Efficacy at the Site of Disease

Waltham, MA, July 12, 2012 – Kala Pharmaceuticals, Inc., a leading developer of innovative products that rapidly and effectively penetrate the mucosal barrier to treat a wide range of debilitating diseases, announced a publication by company co-founder Justin Hanes, PhD in *Science Translational Medicine* showing promising effects of its Mucosal-Penetrating Products (MPPs) in preventing Herpes Simplex Virus-2 (HSV-2) infection.

In the paper titled “Mucus-Penetrating Nanoparticles for Vaginal Drug Delivery Protect Against Herpes Simplex Virus,” Dr. Hanes and collaborators at Johns Hopkins University School of Medicine conducted preclinical studies that included acyclovir-MPP, Kala’s innovative therapeutic engineered with the anti-HSV drug, acyclovir. The studies demonstrated that MPPs improve mucus penetration and drug retention, enabling the acyclovir-MPP to achieve greater efficacy at one tenth of the dose compared to conventional acyclovir.

“Mucosal barriers have been largely overlooked as a limitation for drug efficacy. These data show how Kala’s MPP approach can open up new possibilities for more effective medicines,” commented Robert Langer, ScD, another Kala co-founder and the David H. Koch Institute Professor at MIT. “Kala’s technology can be used to engineer innovative therapies with the size and surface coating properties necessary to dramatically improve drug penetration and retention in mucosal tissues leading to the potential for significantly enhanced therapeutic outcomes.”

Key findings of the published study include:

- Upon challenge with HSV-2, Kala’s acyclovir-MPP protected 53% of the mice from infection compared to only 16% of those treated with conventional acyclovir at the same dose. In fact, acyclovir-MPP demonstrated greater efficacy at one tenth of the dose compared to conventional acyclovir.
- Acyclovir-MPP was shown to be both non-toxic and safe after daily vaginal administration.
- Kala’s MPPs achieved rapid coating of the cervicovaginal surface in mice, including distribution into the deep vaginal folds, within 10 minutes of therapeutic administration. The MPP showed not only greater, but also much more uniform coverage in coating the mucosal tissue when compared to a conventional formulation.
- The MPPs also remained in place for at least 24 hours enabling the potential for a once daily therapy.

“These results from Dr. Hanes’ lab at Johns Hopkins University are very encouraging and further expand on previous *in vivo* proof-of-concept studies with Kala’s MPPs in other mucosal tissues including our NIH-sponsored work in the eye and respiratory tract,” said Guillaume Pfefer, PhD, CEO of Kala Pharmaceuticals. “These data show the significant impact that Kala’s therapeutic approach can have in creating highly effective treatments for debilitating respiratory, ophthalmic, female reproductive tract and gastrointestinal diseases.”

About Kala Pharmaceuticals

Kala Pharmaceuticals, Inc. is developing innovative products which are capable of penetrating mucosal barriers for the treatment of major diseases that affect the eyes, lungs, gastrointestinal tract, and female reproductive system. Mucosal barriers have been largely overlooked as a limitation for drug efficacy. Using the company's proprietary technology platform, Kala's Mucosal-Penetrating Products (MPPs) have the unique ability to rapidly and uniformly coat and permeate mucosal tissues leading to highly effective treatments with improved side effect profiles. The company is leveraging its platform as an internal product engine for a wide spectrum of potential applications, including treatments for respiratory, ophthalmic female reproductive tract and gastrointestinal diseases. Kala is also pursuing collaborations with partners to transform the therapeutic properties of marketed drugs and compounds in development. Kala was founded by leaders in the fields of nanomedicine and biopharmaceutical engineering, Dr. Justin Hanes of The Johns Hopkins University School of Medicine, Dr. Robert Langer of the Massachusetts Institute of Technology, and Dr. Colin Gardner formerly of TransForm Pharmaceuticals/Johnson & Johnson and Merck. The company is backed by leading investors including Lux Capital, Polaris Venture Partners, and Third Rock Ventures. For more information, please visit www.kalarx.com.

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