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Mucus-focused Kala hires CEO; prepares to add seed funding in the fall

After 15 years in Big Pharma, Guillaume Pfefer has taken a job as president and CEO of Kala Pharmaceuticals to live out his entrepreneurial dreams just as the early-stage, Waltham, Massachusetts-based company has begun its preparations to select the first product candidate from its Mucosal-Penetrating Products (MPP) platform.

Along with the 12 July announcement that Dr Pfefer joined the company, co-founder Justin Hanes published a paper in Science Translational Medicine that described how Kala's nanoparticles for vaginal drug delivery penetrate mucosal surfaces and protect against transmission of herpes simplex virus-2 (HSV-2).

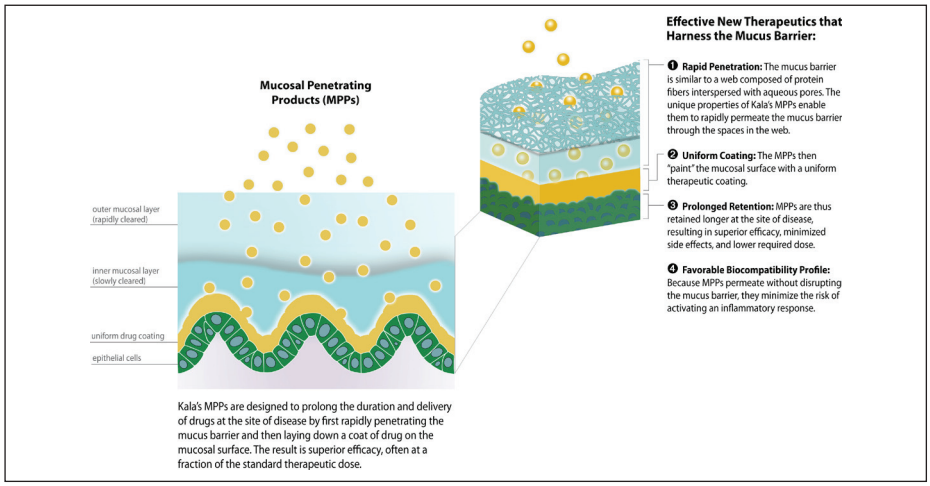
With fresh data on the company's platform in hand, Dr Pfefer said it was the right time and Kala was the right opportunity to apply his engineering background and pharmaceutical experience in innovation, operations and strategy to running an entrepreneurial company.

Dr Pfefer, who previously was the general manager of Sanofi Pasteur Mexico, replaces acting CEO Robert Paul, a co-founder and managing partner at Lux Capital, one of four equity investors that provided $11.2 million in seed funding for Kala. The last $6.2 million of that equity financing closed in March with investments from Lux, Polaris Venture Partners, Third Rock Ventures and Lighthouse Capital Partners.

During the next few months, Dr Pfefer and his colleagues at Kala will sharpen the private firm's strategy and pinpoint the best drug candidates from its MPP platform. The company also plans to collaborate with pharmaceutical partners to improve the therapeutic properties of marketed drugs as well as compounds in development.

"We are in discussions with several companies that have expressed interest in what we are doing," Dr Pfefer said.

Kala's MPPs are designed to uniformly coat and rapidly permeate surfaces covered with moist, sticky mucus, such as the eyes, lungs, intestines and female reproductive system. The company's nanoparticles offer improved distribution, prolonged retention and delivery of a high concentration of medicine at the site of disease for a wide array of drug indications.



Kala's MPPs are designed to prolong the duration and delivery of drugs at the site of disease by first rapidly penetrating the mucus barrier and then laying down a coat of drug on the mucosal surface. The result is superior efficacy, often at a fraction of the standard therapeutic dose.

Kala's newly published data come from preclinical studies conducted by Dr Hanes and his collaborators at the Johns Hopkins University School of Medicine in Baltimore, Maryland for acyclovir-MPP, Kala's reengineered version of the anti-HSV drug acyclovir.

In mouse models, acyclovir-MPP moved quickly through cervicovaginal mucus (CVM), penetrated deep into the vaginal folds within minutes and remained there for 24 hours, while conventional acyclovir particles got stuck in the thick mucus layer. Similar results were observed in human ex vivo models.

Also, only 16% of the animals treated with acyclovir were protected from infection when exposed to HSV-2 compared to 53% of those treated with Kala's preclinical candidate.

"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," said Kala co-founder Robert Langer, a chemical and biomedical engineering professor at the Massachusetts Institute of Technology (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."

The company is investigating the use of its MPP technology in respiratory, ophthalmic, gastrointestinal and female reproductive diseases.

Kala's early funding also includes grants from the National Institutes of Health to study improved inhaled treatments for cystic fibrosis-related infection and better formulations for ocular drug administration.

The company plans to raise additional seed funding in the fall based on its collection of preclinical data that validates the MPP platform.

"We have a very large band of application right now and we have enough clinical data to demonstrate applicability of the technology that we own. Now, we have to develop it into the most effective treatments. We want to make sure we're making a difference and treating disease where there is the most urgent need," Dr Pfefer said. mandy.jackson@informausa.com