

NEWS RELEASE

Scientists Use Live Bacteria to Fight HIV

A novel topical microbicide could provide a “live bioshield” to protect women against HIV

MOUNTAIN VIEW, Calif.; July 18, 2011. Scientists at Osel Inc. and the National Cancer Institute (NCI) have developed a new way to prevent HIV infection by genetically enhancing the ability of naturally occurring vaginal bacteria to block viral transmission. Bioengineered bacteria introduced into the vaginal cavity of macaques—a commonly used experimental primate—reduced the transmission of simian HIV (SHIV) by nearly two thirds.

The novel approach takes advantage of lactobacilli, which are beneficial bacteria that play an important role in vaginal health and help protect women against a variety of sexually transmitted infections. The Osel team engineered the common strain *Lactobacillus jensenii* to pump out therapeutic quantities of the HIV inhibitor cyanovirin-N, which is a protein originally discovered by NCI scientists screening natural substances for antiviral activity.

In a study just published online in advance of publication in the Nature journal *Mucosal Immunology*, the team showed that vaginal administration of *Lactobacillus* expressing CV-N to rhesus macaques could reduce the transmission of SHIV (a virus developed for research that combines critical components of HIV with the ability to infect monkeys) by 63 percent after repeated challenges with virus. A reduction in the viral load was also seen in infected macaques that received the *Lactobacillus* product, called MucoCept.

“We were excited to see this reduced rate of transmission in the macaque model,” said Dr. Laurel Lagenaur, the leader of the Osel team. “Because this *Lactobacillus* strain is likely to colonize women at a higher rate than macaques, we could see an even bigger reduction in the rate of HIV infection when this product is tested in women. The lactobacilli themselves are also beneficial to vaginal health.”

The scientists believe their approach could provide an affordable and durable method for reducing the continuing worldwide epidemic of HIV, which currently infects more than two million people every year. A major advantage of the novel approach of a live bioshield such as MucoCept is that it would provide sustained protection; women would not need to apply it frequently or immediately before sexual intercourse.

“This approach has potential as a novel ‘natural’ approach to prevent HIV,” said Dr. Salim S. Abdool Karim of Centre for the AIDS Programme of Research In South Africa (CAPRISA) at the University of KwaZulu-Natal, who co-led a study establishing proof-of-concept for microbicides using tenofovir gel. “Data in women are eagerly awaited.” Dr. Karim was not involved in the current study.

“It’s exciting to be working on a prevention for HIV that people could actually afford,” said Dr. Dean H. Hamer, chief of the Gene Structure and Regulation Section at the NCI and senior author of the study. “While there is much interest in the recent results with PrEP [pre-exposure prophylaxis], it’s important to realize that the cost of the required antiretroviral drugs is prohibitive in the real world.”

The engineered lactobacilli in MucoCept constitute an ideal microbicide because the organisms naturally colonize the vagina—unlike the strains found in dairy products or food supplements—and they continuously produce the HIV inhibitor. Upon administration of MucoCept as a vaginal suppository, these bacteria can take up residence and potentially protect the user for weeks at a time.

The Osel group is hoping to start human trials of MucoCept within the next several years following completion of product development and safety testing.

These studies were funded by the National Institutes of Health, under federal grants from NIAID and DMID. The MucoCept HIV project has also been supported by CONRAD-GMP, IPM, USAID, and the Bill and Melinda Gates Foundation.

REFERENCE: *Mucosal Immunology*; Advanced Online Publication July 6, 2011

<http://www.nature.com/mi/journal/vaop/ncurrent/full/mi201130a.html>

About Osel, Inc.

Osel Inc. is a biopharmaceutical company with a proprietary technology platform to develop next-generation probiotics as pharmaceutical products. In addition to MucoCept, Osel is developing an unmodified *Lactobacillus crispatus* product, LACTIN-V, as a natural antimicrobial-sparing intervention to prevent several common urogenital infections in women, including recurrent urinary tract infections (RUTI) and bacterial vaginosis. LACTIN-V was recently shown to reduce the rate of recurrent urinary tract infection in women by about one-half ([Stapleton et al., Clin Infect Dis. 52:1212-1217, May 2011](#)), which compares favorably to antimicrobial prophylaxis, the current standard of care for RUTI. MIYA-BM, containing the novel probiotic bacterium, *Clostridium butyricum* MIYAIRI 588, is an oral product in clinical development for the prevention of antimicrobial-associated diarrhea and *Clostridium difficile* infection. For further information, visit www.oselinc.com.

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