



Osel, Inc.'s Lead Product LACTIN-V Enters Phase 2b Study to Prevent Recurrence of Bacterial Vaginosis

-- Company focused on microbiome-restoring therapies and preventions for women's health --

Mountain View, CA (May 11, 2016): Osel, Inc. today announced the initiation of a Phase 2b clinical study of its lead product candidate, [LACTIN-V](#), to prevent the recurrence of bacterial vaginosis following antibiotic therapy. LACTIN-V is a live biotherapeutic product that contains a naturally occurring *Lactobacillus* strain that is part of the vaginal microbiome of healthy women and used to restore the vaginal microbiota and prevent recurrence of infection.

The double-blind, placebo-controlled study, being conducted at four centers throughout the United States, will enroll over 200 women to estimate the efficacy of LACTIN-V compared to placebo in preventing recurrence of bacterial vaginosis. A secondary endpoint of the study will be to investigate the colonization of the beneficial bacteria during the period of dosing. Osel expects completion of the Phase 2b study in early 2018. The study is sponsored by the National Institute of Allergy and Infectious Diseases in collaboration with the University of California, San Francisco (UCSF) and other clinical sites.

“Currently the only FDA-approved treatments for bacterial vaginosis are antibiotics. Antibiotics affect not only pathogenic bacteria but also the beneficial bacteria in the microbiome, often leading to further imbalance and dysbiosis,” said K.T. Moortgat, PhD, Chief Executive Officer, Interim, of Osel, Inc. “We are eager to move LACTIN-V forward in the clinic for evaluation as a restorative to the vaginal microbiome following antibiotic treatment.”

Bacterial vaginosis (BV) is the most common vaginal infection in women ages 15-44, according to the Centers for Disease Control and Prevention, with a prevalence of over 29%. While infected women often report no symptoms, they are at markedly higher risk for other sexually transmitted disease and when pregnant, have higher rates of pre-term birth. The approach to treating bacterial vaginosis has not changed in several decades, and recurrence rates are high even following successful treatment.

“Up until now, patients have lacked optimal treatment to prevent recurrence of bacterial vaginosis,” said Craig Cohen, MD, MPH, Professor of Obstetrics, Gynecology and Reproductive Sciences at UCSF and clinical lead for the trial. “My team and I are excited that LACTIN-V will be further evaluated in this Phase 2b study for its ability to address this important clinical need. If LACTIN-V is proven efficacious, clinicians will finally have an improved therapy to prevent BV by promoting a natural *Lactobacillus*-dominant vaginal microbiome.”

LACTIN-V is the most advanced product candidate in Osel’s portfolio of microbiome-modulating products. It incorporates a single strain of *Lactobacillus crispatus* and is delivered intravaginally via a proprietary applicator. LACTIN-V is designed to restore the healthy vaginal microbiota to combat pathogenic bacteria and the dysbiosis that are seen in bacterial vaginosis.

For more detail on this trial, and information on how to participate, please visit <https://clinicaltrials.gov/ct2/show/NCT02766023?term=LACTIN-V&rank=1>

About Osel, Inc.

Osel, Inc., a privately held biotechnology company, is focused on the development and commercialization of a portfolio of Live Biotherapeutic Products (LBPs) that prevent or treat medical conditions resulting from a disruption of the human microbiome. In 2003, Osel became one of the first companies to receive U.S. Food and Drug Administration authorization to test a live bacterial therapeutic, and the company is a pioneer in the field of LBPs. The company’s proprietary approach identifies differences between healthy and disease-related microbiomes and leverages beneficial microbes to treat problematic disruptions or dysbioses. Osel’s approach repopulates the disrupted microbiome with beneficial bacteria that help restore a healthy and protective microbiota.

Osel’s primary focus is women’s health, with initial areas of interest including recurrent urinary tract infections and bacterial vaginosis. Osel is based in Mountain View, CA. For more information, please visit the company’s website at <http://oselinc.com>

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For patients: <https://clinicaltrials.gov/ct2/show/NCT02766023?term=LACTIN-V&rank=1>

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