

# New hope for BV patients

There is a huge unmet medical need for improved products to treat Bacterial Vaginosis (BV), the most common gynaecological infection.

**BACTERIAL VAGINOSIS** (BV) is caused by an imbalance of the naturally occurring bacterial flora of the vaginal mucosa, resulting in increased vaginal alkalinity (too high pH), inhibition of the normal lactobacilli growth and excessive discharge with a strong foul fishy odour. It is the most common type of gynaecological infection in women and accounts for about half of all vaginal infections. BV has a prevalence of 10-30%. It often reoccurs several times per year, and 6% of the women get BV as often as once a month.

Feelings of unfreshness and embarrassment deter women from having sex and some women even isolate themselves socially, due to odour and excessive discharge.

Panty shields are used on a daily basis among many of these women. Despite this negative impact on many women's lives, few seek help for this problem at a gynaecologist.

"A survey of 256 women in Sweden that we conducted in December 2008 to January 2009 showed that the majority of the women do not seek help from a gynaecologist for their BV problems. A couple of reasons among others are that it's awkward and also time consuming to go to the gynaecologist, especially if appointments are needed several times per year due to recurrences of BV. The survey confirmed much of what we already knew about women's perception of BV. Women suffering from BV want to have

a product that is long-lasting, easy to administer and use and which does not require a prescription from a gynaecologist," says Jeanette Sundberg, Managing Director of Laccure AB, a project company in P.U.L.S. AB's portfolio.

"Therapies currently available on the market are dominated by antibiotics, both oral and topical, and many women are aware of the problem of inappropriate over-use of antibiotics causing bacterial resistance and lowering of the immune system, as well as knocking out bacterial cultures in the body that you want to keep etc. Physicians are also restrictive in prescribing antibiotics," she adds.

## Slow release of lactic acid

Antibiotic treatment is sometimes combined with pH-lowering products to correct the natural acidity and to prevent recurrence. However, current products are based on gels that are messy and difficult to administer, and most of them need to be applied daily since they leak out. Gynaecologists therefore have limited treatment options to prescribe or recommend to women suffering from BV. There is thus a huge unmet medical need for improved products on the market.

"This was the starting point when one of our innovators, a gynaecologist himself, addressed this problem. Discussions with colleagues and partners of PULS eventually led to the founding of Laccure in 2007. What our innovators were aiming at was a product that is long-lasting and provides easy self-administration," says Jeanette Sundberg.

Laccure's innovation is based on a chemical modification of lactic acid resulting in lactic acid release over an extended period of time. The product will be ideally placed to take advantage of the trend towards non-antibiotic, user-friendly, non-prescription products for bacterial vaginosis.

The product is being developed with pharmaceutical quality. The patient performance, safety and efficacy will be documented in clinical trials. Laccure intends to bring the product through all necessary requirements for CE-labelling in the EU and then sell the product in its entirety to an industry partner for further commercialisation.



**JEANETTE SUNDBERG**, Managing Director of Laccure AB.