

Peptonic Medical has gotten approval to start a clinical trial for the treatment of vaginal fungal infections with an adapted version of VagiVitalâ AktivGel

Peptonic Medical AB (publ) ('Peptonic' or 'the Company') today announces that the Company has received approval from the Swedish Medical Products Agency as well as the Ethics Committee to start a clinical study to evaluate treatment of patients with recurrence of fungal infections.

The study will be carried out at Karolinska University Hospital Huddinge with Associate Professor / Gynecologist Aino Finanu Jonasson as principal investigator. The study is expected to start by the end of August 2021. The product used in the study is an indication-adapted version of the CE-marked gel VagiVital® AktivGel for vaginal atrophy. The rationale behind the application is positive results from in vitro studies showing an effective antifungal effect.

• Women suffering from fungal infection have spontaneously tried VagiVital® AktivGel informing us about positive results. Based on this we have reason to believe that we should see positive clinical results with a gel that has been further optimized for the indication, says Erik Sundquist CEO Peptonic Medical.

Initially, a pilot study with 20 patients will be conducted. The effect is evaluated after 7 and 30 days of treatment. Thereafter, a placebo group will be included as reference, the placebo group will be untreated. In the second part of the study, more than 100 patients are planned, including the placebo patients. The pilot study is expected to be completed by the end of 2021, the entire study is expected to include the last patient during the summer 2022.

During a lifetime, 75% of all women will have at least one episode of a fungal infection whereas 40-50% will have recurrent episodes. Most infections are treated with an antifungal drug that is applied vaginally or taken orally. As per above some patient groups experience problems with recurrence, others have problems with side effects and still others simply do not want to be treated with a pharmaceutical drug.

Most vaginal fungal infections are mild, however, some women can develop serious infections with redness, swelling and fissures in the vagina. Women who are more likely to get a vaginal fungal infection include those who are pregnant, use hormonal contraceptives (such as birth control pills), have diabetes, have a weakened immune system (for example due to HIV infection or have drugs that weaken the immune system such as eg steroids and chemotherapy) as well as those taking or who have recently taken antibiotics.

Vaginal fungal infection is usually diagnosed by examining vaginal secret under microscope at the doctor's office and/or sending the sample for fungal culture test at a laboratory. A positive fungal culture does not always mean development of symptoms as some women can get vaginal fungal infection without notable symptoms.

• There is a treatment gap for women who have recurrence of vaginal candidiasis. There are also needs for women having problems with side effects after drug treatment or simply do not want to be treated with drugs. We already know that the basic gel in VagiVital has a fantastic safety profile and we see great opportunities for a clinically proven self-care product against candida based on an adaptation of our gel, says Erik Sundquist

This disclosure contains information that PEPTONIC Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 15-07-2021 17:22 CET.

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About Peptonic Medical AB

Peptonic Medical AB (publ) is an innovative biomedical company that conducts research on and development of drugs and medical devices in the field of women's health. Our vision is to offer safe and effective treatments for women-specific diseases and medical conditions. Peptonic Medical launched VagiVital® in July 2018. This is a hormone-free product for the treatment of vaginal atrophy and vaginal dryness. The company's development program also includes Vagitocin® - a product that contains oxytocin for the treatment of vaginal atrophy. The development of Vagitocin® has been put on hold pending new information regarding the mechanism of action of oxytocin in this indication. The company was founded in 2009 and the share has been traded since 2014 on Spotlight (www.spotlightstockmarket.com, short code: PMED) in Stockholm.

Since August 2020, Lune Group Oy Ltd. is a wholly owned subsidiary of the Peptonic Medical. Lune Group Oy Ltd. is a company founded by Heli Kurjanen in 2005. The company's business concept is to lead a menstrual revolution in a positive spirit. By focusing on sustainable development, environmental issues and the promotion of sexual health, the company has developed to take the lead for the menopausal companies. Lunette® menstrual cups are an alternative to disposable menstrual protection and last for several years. The company has resellers in 50 countries and sells Lunette products to over 100 countries via its web shop. Lune Group has in the USA the subsidiary Lune North America Inc. Lunette® menstrual cups are designed, manufactured and packaged in Finland. For more information about Lunette®, visit www.lunette.com.