A great milestone reached in the Gedea Biotech's NEFERTITI Clinical Trial of pHyph for antibiotic-free treatment of women with bacterial vaginosis

Uppsala, Sweden, February 2, 2021 – LINK Medical, the Northern European clinical research organization (CRO), and the Swedish women's health company Gedea Biotech announced today that it has enrolled the first patient in the NEFERTITI clinical study of its lead product, pHyph, a vaginal tablet for topical treatment of bacterial vaginosis (BV). The randomized double-blind placebo-controlled study is designed to confirm safety and efficacy of pHyph and is coordinated by Nottingham University NHS Hospitals Trust in the UK and LINK Medical.

Bacterial vaginosis is a vaginal infection with a prevalence of 10-30% in adult women. The infection causes disturbing symptoms that affects daily life in many ways. NEFERTITI aims to recruit 150 adult women aged 18 or over with bacterial vaginosis diagnosed by Amsel's* criteria. The primary objective is to investigate clinical performance of pHyph. After the first treatment period (day 0-7), patients that are cured (a high cure rate is expected based on a previous smaller study), will be randomized to preventive treatment, and given one tablet a week of pHyph or placebo, for four months. The follow up period will provide important data on pHyph´s impact on prevention of recurrent infections and the effect on the vaginal microbiome. Patients in the UK and in Sweden will be enrolled in the NEFERTITI study.

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>
> - Ola Gudmundsen

"LINK Medical is proud to be a strategic partner, supporting Gedea in improving their strategy which has helped with the planning of their clinical trials as well as to get funding from the EU program Fast Track to Innovation (FTI), part of Horizon 2020. Today we celebrate reaching another very important milestone after a year overcoming challenges with Covid-19. With 4 sites in the UK and 3 sites in Sweden we are ready to get this clinical trial running with a great team. We are looking forward to positive results in this transformational treatment for women" says Ola Gudmundsen.

"I am delighted to lead the NEFERTITI study as the Chief Investigator," commented Dr Kate Walker, Clinical Associate Professor in Obstetrics, University of Nottingham. "Bacterial vaginosis is a very common vaginal infection, affecting 1-2 in every 10 women, caused by an overgrowth of unhealthy bacteria in the vagina. We have standard antibiotic treatments which work really well in the short term, but there is a very high rate of recurrence. This results in women having to take multiple courses of antibiotics which contributes to the global problem of bacteria becoming resistant to antibiotics. It would be a major step forward to have a non-antibiotic treatment that cures women and prevents recurrence. That's why I'm so excited about the NEFERTITI trial as we may have found such a new treatment. It's really important to do the study properly and check the treatment is effective and acceptable to women."

Annette Säfholm, Gedea Biotech's CEO comments: "In a smaller study reported last year 82% of the women were clinically cured, defined as absence of all Amsel criteria, after 7 days, thus corresponding to the outcome of existing antibiotic-based treatment. This larger trial will be pivotal in confirming that pHyph can provide an effective and long-lasting treatment alternative to antibiotics."

**Diagnose of bacterial vaginosis according to Amsel criteria is at least three of the following criteria – thin white homogeneous discharge, clue cells on microscopy, pH of vaginal fluid above 4.5. and release of a "fishy" odor.*

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About bacterial vaginosis

Bacterial vaginosis is the most common vaginal infection in women of reproductive age and is a disease of the vagina caused by excessive growth of bacteria producing an imbalance of the naturally occurring bacteria in the vagina. The condition is treated with antibiotics and/or antiseptic treatment products. Recurring bacterial vaginosis is common.

About pHyph

The vaginal tablet, pHyph acts restoring the vaginal pH to its normal level of pH 4,0 - 4,5 and by breaking down the biofilm formed during bacterial vaginosis under which the infectious bacteria begin to thrive. The naturally occurring active ingredient GDA 001 in pHyph is well documented and is already approved as a food additive.

About Gedea Biotech

Gedea Biotech is a Swedish, innovative women's health company developing pHyph, the first antibiotic free treatment that both prevents and treats bacterial vaginosis. Vaginal infections affect at least 400 million women every year worldwide and the market is worth over $ 1.5 billion. Gedea Biotech was founded in 2015 in Lund, Sweden. https://gedeabiotech.com/.

About LINK Medical

LINK Medical is a full-service contract research organization (CRO) providing product development services for the pharmaceutical and medical device industries across Northern Europe. We offer a well-integrated local presence in all Nordic countries, UK and Germany. Reaching from early phase development to post-marketing, we have over 200 employees providing expert guidance across every aspect of a project – all from ONE source. Our promise is to improve and accelerate your product development through transformative methods, active communication and optimal solutions. As a strategic partner, we provide expert competence and technology to enable evidence-based decision-making that supports the delivery of superior clinical outcomes.

About research at Nottingham University Hospitals NHS Trust

Nottingham University Hospitals NHS Trust is one of the biggest and busiest acute hospitals in England, employing over 16,000 staff. We provide care to over 2.5million residents of Nottingham and its surrounding communities and specialist services to a further 3-4million people from neighboring counties. We are one of the most research-active Trusts in the country with world-leading clinical research delivered across our hospitals through over 400 clinical trials a year. Our NIHR Nottingham Biomedical Research Centre is translating research discoveries into new treatments for common diseases including asthma and arthritis. Central to our research is our expertise in Magnetic Resonance Imaging (MRI). Supporting this is the NIHR Nottingham Clinical Research Facility which provides the infrastructure, skills and knowledge essential to the delivery of high-quality research into experimental medicine for adults and children.