

Last study subjects of Peptonic Medical's phase 2b study ready for enrolment

Stockholm, October 25th, 2016 – Peptonic Medical AB (publ) (“Peptonic” or “the Company”) – a company developing pharmaceuticals based on oxytocin – today announced the last study subjects of the ongoing phase 2b study now have been signed up to be enrolled. The last patient is expected to enter the study within a fortnight. In total, 160 study subjects are participating in the study, the objective of which is to investigate the effect of Peptonic Medical’s candidate drug Vagitocin® in the treatment of vaginal atrophy in post menopausal women. In this study, a glass syringe is used for containing and administration of the vaginal gel.

“It feels good to have all patients recruited for this study. The in-flow of patients slowed down during and after the summer due to a weaker response to patient recruitment advertising. This has led to an adjustment of the study time plan”, says Johan Inborr, CEO of Peptonic, “Despite this slippage in the time plan, it’s comforting and encouraging that we keep recruiting study subjects according to the inclusion criteria, that the study progresses well both technically and logically, and that study costs are kept within the budget”.

In addition to the clinical phase 2b study, recruitment for a smaller, a so called explorative study (40 study subjects), continues without delay and is expected to be completed by mid December. The clinical endpoints are the same as in the main (phase 2b) study, but the glass syringe will be replaced by a laminated tube and a disposable applicator is used for administration of the vaginal gel. The laminated tube is cheaper and commercially a more attractive option than the glass syringe.

Initial results from the two studies are expected during Q1 2017.

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About Peptonic Medical AB (publ)

Peptonic Medical AB (publ) is an innovative Swedish pharmaceutical company developing oxytocin based products e.g. for the treatment of menopausal symptoms, such as vaginal atrophy. Oxytocin has a long history of safe medical use and offers an alternative to estrogen and estrogen-like acting compounds for menopausal and postmenopausal women. Peptonic Medical AB (publ)’s mission is to develop safe and effective drugs based on oxytocin.

About the Phase 2b clinical study

The Phase 2b study is a double-blind, placebo-controlled, multicenter study and comprise two arms of 80 patients each, in total 160 patients. The objective of the study is to investigate the effect of Vagitocin® (oxytocin 400 IU/day) compared to placebo for the treatment of vaginal atrophy. The Vagitocin® gel is stored in glass syringes and refrigerated during the study. In an exploratory part of the study, comprising 40 study subjects, the Vagitocin® gel is stored in a laminate tube and refrigerated.

Three clinical centres in Sweden are participating in the clinical study. Associate professor Aino Fianu Jonasson, at the Department of obstetrics and gynecology at the Karolinska University hospital in Huddinge, is the principal investigator of this clinical study.